



# Radiation dose optimization in interventional radiology and cardiology using diagnostic reference levels

Hendrik Johannes de Vos

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Supervised by Dr TC Kotzé & Mr CJ Trauernicht associated with the  
Department of Medical Physics, University of Cape Town

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## **ABSTRACT**

**Purpose:** The International Commission of Radiological Protection (ICRP) advises that in principle Diagnostic Reference Levels (DRL) could be used in fluoroscopically guided interventional procedures to avoid unnecessary stochastic radiation risk. The increase in complexity of interventional procedures, combined with a lack of specialist training on radiation techniques, poses a significant risk to patients. These risks have not gone unnoticed by government authorities worldwide and in 2015 the South African Department of Health: Directorate Radiation Control issued requirements to license holders of interventional fluoroscopy units, requiring that a medical physicist optimize their radiation usage using DRLs. The Dose Area Product (DAP) quantity measured for each patient represents a dosimetry index, the value of which for the purpose of improvement should be optimized against the DRL. In this dissertation, I aim to establish if DRLs in the South African private healthcare interventional theatres are high compared to international levels and whether DRLs will optimize the doses used.

**Materials and methods:** Standard interventional procedures performed in 27 private hospitals' vascular, cardiac and electrophysiology interventional theatres were identified and included in this dataset. Each entry in the database includes a procedure description, the Dose Area Product (DAP) and the screening time. The 3rd quartile of the distribution was used to calculate DRLs. The mean international DRLs for the different cases were calculated and compared with local levels. A Log<sub>10</sub> t-test was used to evaluate if dose was optimized or not.

**Results:** Dose and exposure data was recorded in 6 quarters which included 20415 procedures performed from July 2012 to December 2013. This included 3911 data

points for Coronary Angiograms (CA), 7547 Coronary Angiograms & Left Ventriculography (CA+LV), 1885 CA + Percutaneous Trans-luminal Coronary Angioplasty (PTCA) + 1 Stent, 1175 Permanent Pacemakers (PPM), 280 biventricular PPM and 675 radiofrequency ablation cases. DRLs were calculated for the above procedures with high case numbers. The 2012 DAP values were used as a baseline for this study and the DAP values recorded at the end of 2013 as current results. Standard deviation, 1st & 3rd quartiles and inter-quartile ranges were calculated. DRLs determined for procedures includes: CA (57.0 Gy.cm<sup>2</sup>), CA+LV (63.5 Gy.cm<sup>2</sup>), CA + PTCA + 1 Stent (176 Gy.cm<sup>2</sup>), PPM (36.2 Gy.cm<sup>2</sup>), biventricular PPM (117 Gy.cm<sup>2</sup>) and radiofrequency ablation (65.7 Gy.cm<sup>2</sup>).

**Conclusion:** The DRL for these six procedures improved between 9 - 45 % and the t-test results confirmed this hypothesis for all procedures except biventricular PPM. We attribute the improvement seen to various factors, including increased awareness, changes in imaging techniques, new and upgraded imaging equipment and the improvement of incident management. The mean of international levels published was higher than the DRLs calculated in this work. This means South African private sector interventional doses are not high compared to international levels. Based on the number of cases recorded and the national spread of the participating private hospitals, I propose that these DRLs calculated could be considered as national guidance to interventionists attempting to optimize their techniques through DRLs in South Africa.

**Keywords:** Diagnostic Reference Level (DRL), Dose Area Product (DAP), Interventional Radiology, Interventional Cardiology, Interventional Theatre

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# CHAPTER 1 INTRODUCTION

## 1.1 Introduction

*Are radiation doses used in South African private healthcare interventional laboratories high compared to those published internationally and will establishing dose reference levels optimize the doses used?*

Radiation is widely used in medicine for diagnostic, interventional or functional imaging and for radiotherapy. Since the discovery of the Roentgen ray late in the 19<sup>th</sup> century the use of radiation has helped clinicians to diagnose and treat a vast array of conditions and malignancies. The benefit of these modalities is unequalled in modern hospitals and has led to x-ray imaging being utilised throughout the entire hospital and it is no longer confined to the radiology department.

Today's X-ray imaging equipment mostly utilizes digital technology which has obvious advantages because of the wide dynamic range and ease of use. Many specialist doctors in various disciplines are using and relying on x-ray imaging to perform surgeries and clinical procedures on patients. Unfortunately digital x-ray technologies can lead to overexposure of patients.(1)

Interventional cardiology, being less invasive than surgery, offers great benefit to patients. These specialists, specifically in cardiology and those doing vascular procedures, perform complex surgeries under fluoroscopic guidance which can cause high peak radiation doses to the patient's organs. (2, 3)

Patients that receive interventional cardiology or vascular procedures have a better prognosis, because the interventional techniques are less invasive than traditional

surgery, which in turn lowers the chance of infection. Another benefit to interventional surgery is that the patient recovers quicker than they would after traditional surgery, which leads to shorter hospitalisation and lower costs associated with procedures. (4) For some patients interventional cardiology is the only option, because of age, pathology or co-morbidities and because they may likely not survive invasive surgical intervention. (5, 6)

Ionizing radiation imaging carries with it a risk to the patient and has the potential to cause stochastic and deterministic adverse radiation effects. (2, 7) Deterministic tissue effects materialize when threshold doses are exceeded and some examples thereof are erythema, dermal atrophy and necrosis. (8)

X-ray units in interventional radiology typically have an energy range of between 40 kV – 150 kV. At this X-ray energy skin reactions are the most prevalent deterministic effect, because this is the organ that receives the most radiation dose during a fluoroscopic procedure. In megavoltage radiotherapy where higher energy photons deposit their peak dose to deeper tissue, skin sparing is possible. Even so, skin reactions are common in radiotherapy treatments because of the high dose ranges required to treat tumours. (9)

Management of these reactions is possible to lessen the extent of injury during the course of treatment. (10, 11) Interventional procedures done using fluoroscopy guidance do not commonly exceed deterministic threshold doses for routine procedures, but it is possible for long complex cases or when poor radiographic technique is used. (2, 3, 12, 13)

The classification of stochastic effects or random radiation effects has no threshold dose and some examples are radiation induced malignancies or cancer, infertility

and birth defects. Stochastic effects are not as easily measurable as deterministic effects, because there is no threshold dose indicating possible effect and no assurance, especially at low doses, that an effect is related to the exposure received. (7, 14)

Interventional cardiologists have a high usage of interventional x-ray machines, but unfortunately their training does not include as much radiation physics or radiation safety as that of radiologists. (15) One result of the lack of training may be that interventionists are unaware of the amount of radiation dose to the skin, even today on modern technology.(3) Interventional procedures are becoming increasingly more complex in many specialities, as the types and uses of catheters become more advanced.(5, 16)

The dangers related to diagnostic imaging and specifically the deterministic skin reactions possible during extended fluoroscopically guided procedures has not gone unnoticed by governments and authorities responsible for the safe use of these modalities.

In South Africa, since 2007, it has been regulated that Dose Area Product (DAP) meters be incorporated in fixed fluoroscopy units installed and that the DAP readings be recorded for each patient. This is specified in the electronic product licensing requirements issued by South African Department of Health, Directorate Radiation Control (DoH DRC).(17)

In 2012 DoH DRC imposed further changes to regulations, mandating the license holder to ensure that radiation doses are optimized during clinical procedures. In 2015 additional requirements were issued to license holders of interventional

fluoroscopy units, requiring the use of an medical physicist to optimize their radiation usage using DRLs.(17)

The increase in complexity of interventional procedures combined with a lack of specialist training on radiation techniques poses a significant risk to patients.

Currently, in the South African environment, there are limited publications referring to DRLs with no full publications addressing interventional cardiology. These factors set the stage for this study and emphasize its need.

In this study, I aim to establish if DRLs in the South African private healthcare interventional theatres are high compared to international levels and whether DRLs will optimize the doses used. Additionally I am confident to propose national DRLs for common interventional procedures specific to the South African population in the private healthcare sector.

## CHAPTER 2 LITERATURE REVIEW

### 2.1 Biological Effects of X-rays

The history of radiation and the discovery of X-rays in 1895 by Wilhelm Roentgen have been inundated by publications describing the biological risks because of its use. (3, 14, 15, 18, 19) In the early years of radiation use in medicine there were various and conflicting theories attempting to explain the physical or be it chemical response and resulting damage to tissue. (20-22)

Ionising radiation produced by interventional radiology has the ability to penetrate tissue and deposit energy in cells. (23) This deposition of energy causes, on a cellular level, biological effects within the structural components of cells. These biological effects can be damaging to cells and can lead to different types of cellular response due to the radiation dose received. (2, 3, 24)

The type of radiation and the dose thereof impacts the cellular response. (25) A further danger of radiation is that the damage caused by X-rays does not stimulate the human sensory system nor does it cause noticeable heat sensation to the patient being imaged. (3)

Radiation effects are broadly classified into deterministic and stochastic effects. The ICRP 103 defines a deterministic effect as *“An injury in populations of cells, characterised by a threshold dose and an increase in the severity of the reaction as the dose is increased further. Also termed tissue reaction.”* (26) As noted in this definition deterministic tissue effects materialize when threshold doses are exceeded

and, importantly, the severity of these effects are related to the amount of dose received.(8)

Wagner *et al.* (23) discuss various potential biological effects resulting from radiation dose during interventional procedures, but the most prevalent effect is that of the skin. Listed in Table 2.1.1 are some examples of likely skin reactions, which include erythema, dermal atrophy and even dermal tissue necrosis.

X-ray units in interventional radiology typically have an energy range of between 40 kV – 150 kV. At this x-ray energy skin reactions are the most prevalent deterministic effect, because it is the organ that receives the most radiation dose during a fluoroscopic procedure.

Salvo *et al.* (27) states that approximately 85% of patients treated with radiation therapy will experience a moderate-to-severe skin reaction. These skin reactions often include itching, pain, delays in treatment, discoloration of appearance.

Subsequently most deterministic skin reactions lead to a decrease in quality of life. Management of deterministic reactions is possible and this can lessen the extent of injury during the course of treatment. (10, 11, 28)

Unlike in megavoltage radiotherapy, interventional procedures done using fluoroscopy guidance do not commonly or routinely exceed deterministic threshold doses. Yet it is possible for long complex cases or when poor radiographic technique is used. (2, 3, 12, 13, 29)

As per the ICRP definition of a deterministic effect, the severity is directly related to the skin dose received. Table 2.1.1 displays the possible type of effect relevant at different peak dose levels to the skin. The first sign of effect is noted by Wager *et al.*,

(3) as being transient erythema of the superficial dermal layers at a dose of 2 Gy. This level may be seen as being the threshold dose as described in the ICRP definition of a deterministic effect. (26)

Other authors have proposed different skin threshold dose levels that could lead to a reaction; Wells *et al.* (10) describe the threshold dose as 1.5 Gy. Neofotistou *et al.* (30) proposed a DAP skin reaction investigation level of 300 Gy.cm<sup>2</sup> for interventional cardiology procedures as this could likely cause a skin reaction.

On the end of the spectrum of deterministic skin reactions, Table 2.1.1, shows very severe reactions occurring at doses exceeding 7 - 10 Gy. Various authors have published literature surveys and their experiences with skin reactions in fluoroscopy, some occurring because of repeated procedures and other because of poor radiographic techniques. (2, 3, 31)

Table 2.1.1 indicates the time until the effect would appear, noted as the onset of the reaction. This is very relevant to the possible treatment or monitoring of such an occurrence. Koenig *et al.* (2, 3) list time periods of hours for early transient erythema up to one year for late dermal necrosis and second phase dermal atrophy.

In interventional fluoroscopy, being a less invasive technique, patients generally are fit to be discharged from hospital soon following their procedures. This could lead to radiation induced effects going unnoticed and brings with it the risk of mismanagement of the injury, should a general practitioner or dermatologist not know the cause. (3)

Table 2.1.1: Threshold skin entrance doses for various skin injuries. Table reproduced from Wager *et al.* (3)

Effect	Dose (Gy)	Onset
Early transient erythema	2	Hours
Main erythema	6	~10 days
Temporary epilation	3	~3 weeks
Permanent epilation	7	~3 weeks
Dry desquamation	14	~4 weeks
Moist desquamation	18	~4 weeks
Secondary ulceration	24	~6 weeks
Late erythema	15	~8-10 weeks
Ischemic dermal necrosis	18	>10 weeks
Dermal atrophy (1st phase)	10	>12 weeks
Dermal atrophy (2nd phase)	10	>1 years
Induration (invasive fibrosis)	10	*
Telangiectasia	10	>1 years
Late dermal necrosis	>12	>1 years
Skin cancer	*	>5 years

\* no value indicated in original table.(3)

The ICRP defines stochastic effects of radiation as, “*Malignant disease and heritable effects for which the probability of an effect occurring, but not its severity, is regarded as a function of dose without threshold.*” (26) As noted in this definition stochastic effects, or random radiation effects, have no threshold dose, which means even at very low doses there is a possible risk of a radiation detriment.

The definition notes that the probability of an effect, and not its severity, can be regarded as a function of dose. This alludes to a problem that various authors have explained, being the difficulty to relate the stochastic radiation effect to a delivered dose or procedure. Some examples of stochastic radiation effects are radiation induced malignancies like cancer, or infertility and birth defects. (14, 32, 33)

Predicting the incidence of stochastic effects and relating that to dose has mostly been done using information for accidents or incidents where large populations were exposed to high levels of radiation. Dose levels and cancer incidence were evaluated for atomic bomb survivors of Hiroshima and Nagasaki (34, 35), as well as for nuclear accident survivors of Chernobyl. (36, 37)

In the clinical environment, stochastic effects are not as easily measurable as deterministic effects. This is because there is no threshold dose flagging a possible effect and no assurance, especially at low doses, that an effect is related to the exposure received. (7, 14)

Various authors have attempted to estimate the cancer risk for populations receiving medical procedures, specifically Computed Tomography (CT) and CT angiography. These authors report large variations and uncertainties in the resultant population risk profile, but concur that increased risk is associated with increased dose. They encourage medical professionals to stringently justify radiation usage and to optimize the dose used to essential levels. Because of the late onset of stochastic effects, emphasize is placed on the protection of woman of reproductive capacity and children. (38-40)

In Table 2.1.1., Wagner *et al.* (3), indicates skin cancer as being a possible effect after a time period of five years following exposure. They do not offer a dose level

where this effect would be present, which concurs with the definition of a stochastic effect that may be induced at any dose. The severity is independent of dose, although the probability of occurrence increases as dose increases.

This delayed reaction and uncertainty has led to some clinicians trying to mitigate this risk by monitoring patients. Knautz *et al.* (41) advocate regular follow-up to detect possible malignancies in patients with high radiation doses received during Transjugular Intrahepatic Portosystemic Shunt (TIPS) placement. This premise could be expanded to radiotherapy, long interventional procedures and other modalities using high radiation doses.

Both types of possible reactions to radiation discussed in this section are serious and the consequences of irresponsible use of radiation could be dire for patients. (29)

## **2.2 Justification and Optimization of Dose**

Considering these risks involved in the use of radiation, the principle of justification of use becomes very important. Justification of a procedure involving radiation incorporates not only radiation risk, but many other factors. (42, 43)

The council directive of the European Union explains the principle of justification when using medical radiation as, *“Medical exposure shall show a sufficient net benefit, weighing the total potential diagnostic or therapeutic benefits it produces, including the direct health benefits to an individual and the benefits to society, against the individual detriment that the exposure might cause, taking into account*

*the efficiency, benefits and risks of available alternative techniques having the same objective, but involving no or less exposure to ionising radiation.” (43)*

A well-known term in radiation protection in radiology is “As Low As Reasonably Achievable” (ALARA), which describes the process of safety and optimization for the responsible use of radiation. The ALARA principle goes hand in hand with the concept of justification described by the European council directive. (43)

When radiation is used in medicine, the benefit of the modality needs to be weighed against the possible radiation risk. The ICRP promotes this principle in the management of the safe use of radiation in medicine. (26, 44) The ICRP 105 describes three levels of justification in radiological practice:

1. The first level is a statement that, *“the proper use of radiation in medicine is accepted as doing more good than harm to society.”* This is accepted by the ICRP and not discussed further. (44)
2. The second level of justification is that, *“a specified procedure with a specified objective is defined and justified.”* In the discussion of the second justification level, they emphasize that there must be relevant symptoms or population risk indicators present to justify a procedure. The justification must also consider if the likely condition can be diagnosed and treated. They describe the aim of the second level of justification as, *“to judge whether the radiological procedure will improve the diagnosis or treatment, or will provide necessary information about the exposed individuals.”* (44)

3. The third level of justification is that, “*the application of the procedure to an individual patient should be justified.*” The emphasize being that justification must be to achieve specific objectives considering the characteristics of the individual involved. It is also noted that the justification process should be done before the procedure. (44)

When comparing the NRCR report no 93 (45) of 1986 to the NCRP report no 160 (46) of 2006, it is evident that radiological exposures have increased substantially within this period. The NRCR report 160 describes that doses resulting from medical exposures exceed background dose levels for the population of the United States of America. (47)

Figure 2.2.1, reproduced from the NRCR report 160 (46), shows the breakdown of the radiation dose contribution from different radiology techniques. Computed tomography is the largest contributor, nuclear medicine is the second largest and interventional fluoroscopy third largest. Conventional radiology has the highest incidence of procedures performed, but contributes to the least dose because of lower exposure levels per exam.

The report adds that interventional procedures are fewer in occurrence, but the dose per incidence is higher, which leads to the third highest contributor to population dose. (46) This indicates clearly how lower dose techniques could lead to lower population doses, should they be justified as an alternative to the higher dose techniques.

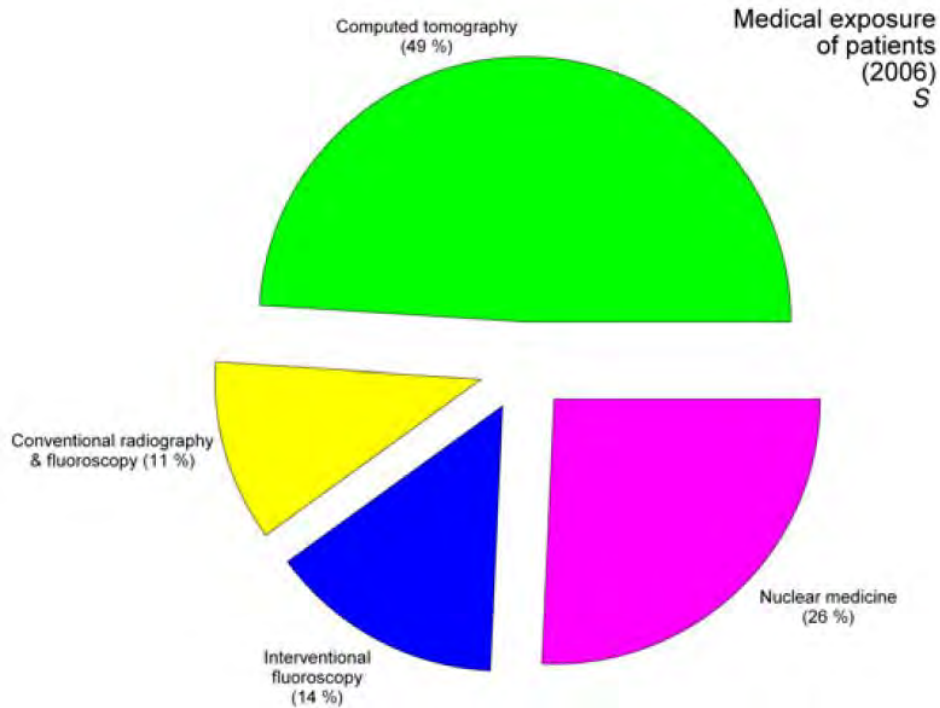


Figure 2.2.1: Distribution of the radiation dose (S) resulting from different types of medical exposures for the patient population in the United States of America in 2006. *Graph reproduced from the NRC report 160. (46)*

Figure 2.2.2 shows the distribution of all interventional procedures performed in the USA as part of the NRC 2006 report. (46) Non-vascular interventional fluoroscopy procedures accounted for 52% of cases performed and cardiology procedures accounted for 28%. Non-cardiac arteriography and vascular procedures were responsible for the remaining cases.

Adding to the increased usage of medical imaging as reported in the NRC report 160 (46), interventional fluoroscopy procedures are becoming increasingly more complex in many specialities. The types and uses of catheters are becoming more advanced, which has led to doctors attempting difficult and long procedures using fluoroscopy.(16, 48)

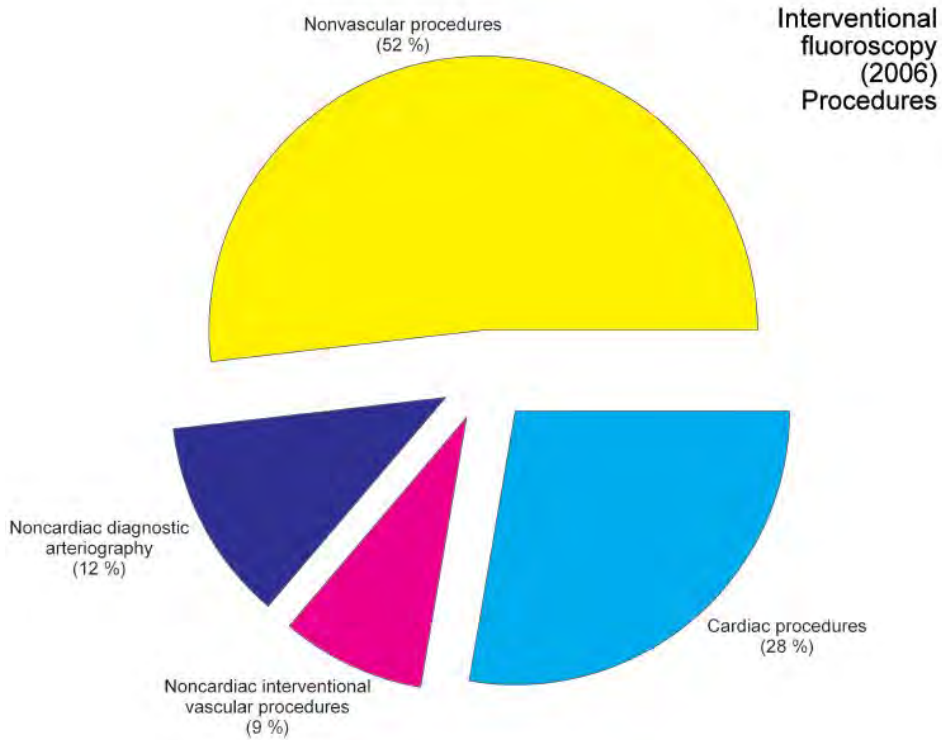


Figure 2.2.2: Distribution of the number of interventional fluoroscopy procedures recorded for the population in the United States of America. *Graph reproduced from the NRCP report 160.* (46)

Until recently, heart valve placement was done through surgical Aortic Valve Placement (AVR), which involves opening a patient's chest cavity to give the surgeon access to the heart valves. Today, in many interventional cardiac theatres, there is an alternative procedure: the Transcatheter Aortic Valve Implantation (TAVI), which is done using special catheters.(49)

This is one example of cardiology, but this notion is seen in many other specialist fields. In neurology, one treatment of an Arteriovenous Malformation (AVM) is to place a combination of glue and coils in the affected aneurysm to minimize the risk of rupture. (50) Another example where high doses are often recorded in vascular units

is when complex Endovascular Aneurysm Repair (EVAR) procedures are done. (51, 52)

The increase in difficulty of interventional procedures, specifically for cardiology, leads to longer procedure times and increased radiation dose usage. Figure 2.2.3 shows the dose contribution to the USA population from the different procedure types. (46)

Cardiology, although only accounting for 28% of all interventional procedures, contributed the highest population dose in this segment. Cardiac procedures contributed 52% of the population dose resulting from all interventional fluoroscopy uses. This shows that the procedures done in cardiology are of significance for dose reduction or when technique optimization and justification are considered.

As seen in Figures 2.2.2-3, cardiology and specifically the interventional cardiologist have a high usage of interventional x-ray machines and the population dose contribution from these procedures is significant. Vlietstra *et al.* (15) noted that cardiologist training does not include much radiation physics or radiation safety training, in contrast to the training received by radiologists. One result of the lack of training may be that specialist doctors using interventional fluoroscopy are unaware of the amount of radiation dose to the skin, even on modern technology. (3)

Considering the risks involved of stochastic and deterministic nature, this lack of training and awareness is unfortunate and could be harmful to patients receiving interventional cardiology procedures.

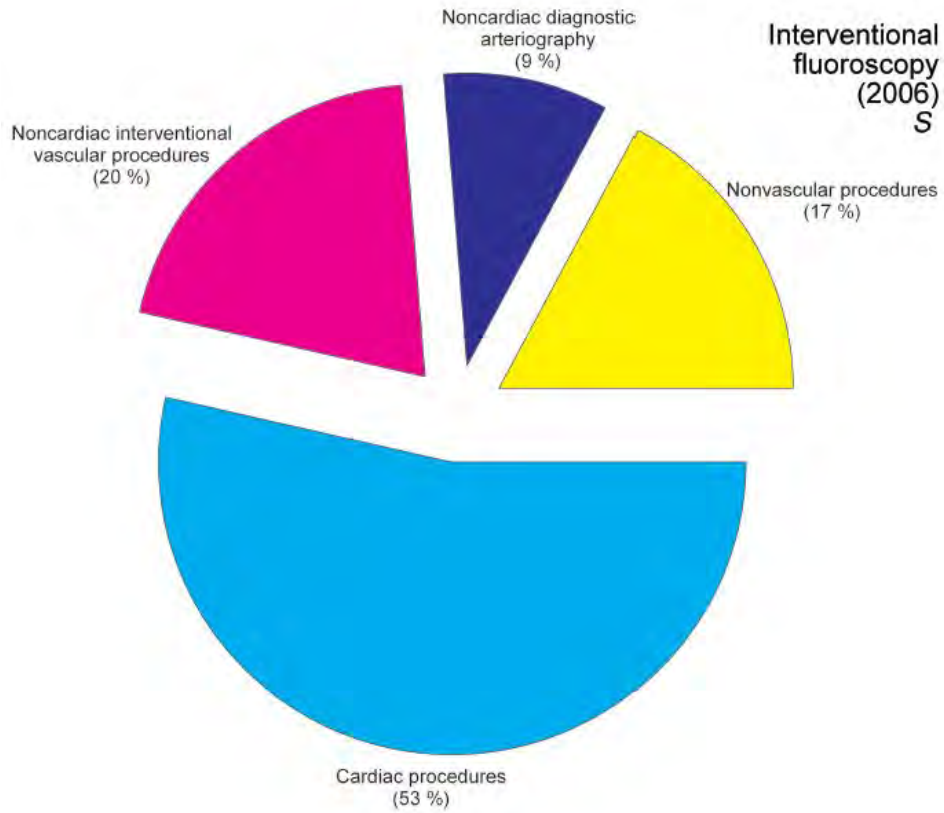


Figure 2.2.3: Distribution of the population dose from the same interventional fluoroscopy procedures recorded in the United States of America. *Graph reproduced from the NRCR report 160. (46)*

## 2.3 Diagnostic Reference Levels

It is reasonable for a patient to assume, when being x-rayed, that standard diagnostic radiology procedures from one population should have similar, or at least comparable, radiation doses. (53) Historic surveys of patient doses have shown that this assumption is incorrect.

Detailed surveys of patient doses as early as the 1950's in the United States and the 1980's in Europe indicate a wide variation in clinical doses needed to perform x-ray examinations. Reports of a variation in doses of as high as twenty fold were described in these initial surveys. (53, 54)

Shrimpton *et al.* (54), concerned by the wide variation in doses seen in the British surveys from the 1980's, published work suggesting guidance doses for medical x-ray examinations in Britain. They suggested that by making simple measurements on samples of patients to obtain dose levels, individual x-ray departments could evaluate their own mean doses compared to these levels. He proposed that if an observation showed that a department significantly exceeds these levels, the radiographic practice should be adjusted or optimized. This could lead to the lowering of doses used at radiographic practises. (54)

The ICRP first introduced the term Diagnostic Reference Level (DRL) in their report 60 (55) and soon followed with detail in report 73 of 1996. (56, 57) This report was later followed by supplementary reports 103, 105 and additional guidance on DRLs. (26, 44, 58)

The European Union Council Directive published in 1997 defines diagnostic reference levels as, *“dose levels in medical radio diagnostic practices or, in the case of radio-pharmaceuticals, levels of activity, for typical examinations for groups of standard-sized patients or standard phantoms for broadly defined types of equipment. These levels are expected not to be exceeded for standard procedures when good and normal practice regarding diagnostic and technical performance is applied.”* (43)

Today the term diagnostic reference level is used widely in medical imaging and the ICRP report 103 published in 2007 has refined this definition as, *“Diagnostic reference level used in medical imaging with ionising radiation to indicate whether, in routine conditions, the patient dose or administered activity (amount of radioactive material) from a specified procedure is unusually high or low for that procedure.”* (26)

Currently, in the international context, the use of DRLs to optimize radiography procedures is not a new concept and various authors and institutions have published DRL data for radiography and even dental radiography. (5, 12, 59-61) There are numerous attempts to establish DRL's for interventional radiology, but one constraint appears to be the restricted amount of procedure types and procedure combinations incorporated in these studies. (62, 63) Interventional DRL's are available internationally for procedures like, e.g. Coronary, Cerebral and Renal Angiography, Left Ventriculography (LV) and Pacemaker Implantations.(64)

The concept of using a DRL in interventional radiology, which includes interventional cardiology, is more complex than for general radiology. The ICRP report 105, and ICRP's additional advice on DRLs, recommends that in principle DRLs could be used in fluoroscopically guided diagnostic and interventional procedures to avoid

unnecessary stochastic radiation risk. This is cautiously said as the ICRP observed that the distribution of doses in interventional radiology is very wide, which may be attributed to the complexity of individual clinical cases. (44, 58)

DRLs form an integral part of dose optimization and if correctly applied can lead to lower population doses. (12, 54, 65) For dose optimization and for the purpose of evaluation the Dose Area Product (DAP) quantity measured for each patient represents a dosimetry index, the value of which should be optimized against the DRL, this varies for each procedure and can be used as a tool to comply with the ALARA principle.(66)

The European Commission provides council directives and guidance to their member states. In their guidance of 1999 (65), the definition of the DRL has not changed since the 1997 council directive (43), but specific guidance is added for the establishment and use of diagnostic reference levels. The 1999 guidance noted the use of the 3<sup>rd</sup> quartile of the distribution to set guidance levels.

This is motivated as being an appropriate method because the DRL distribution curve (histogram) is known as usually being skewed with a long tail representing cases with high doses. Considering the aim of DRLs for optimization, they emphasize that the DRL should be higher than the mean or median of the cases, because this is the level which, if consistently exceeded, should trigger corrective actions. (65)

The 3<sup>rd</sup> quartile method is also noted widely by authors investigating reference level and appears to be the most popular way for determining and comparing DRLs. (5, 63, 64, 67)

In Italy, Padovani *et al.* (68) introduced diagnostic reference levels in 1998 following the European union council directive (43) of the preceding year. They used five cardiology centres in Italy and investigated their most common procedures. They found that for the population of Italy, reference values of 70 Gy.cm<sup>2</sup> for the combined procedure of coronary angiography and left ventriculography and 120 Gy.cm<sup>2</sup> for angioplasty were reasonable recommendations.

In 2004 Aroua *et al.* (69) suggested temporary reference levels in diagnostic and interventional radiology in Switzerland. They used average doses and estimated 3<sup>rd</sup> quartiles from a survey of 257 different types of examinations. Their method of 3<sup>rd</sup> quartile estimations was to multiply mean results with a factor of 1.5 to compare them with 3<sup>rd</sup> quartile DRLs published internationally.

In 2011 Samara *et al.* (67) emphasized the large variation seen in patient exposures in interventional cardiology in Switzerland. They proposed a multicentre 3<sup>rd</sup> quartile DRL of 102 and 125 Gy.cm<sup>2</sup> for Coronary Angiography (CA) and Percutaneous Coronary Interventions (PCI) respectively.

In 2003 Neofotistou *et al.* (30) published preliminary reference levels in interventional cardiology for Europe. They proposed reference levels of 57 and 94 Gy.cm<sup>2</sup> for CA and PCI respectively. Interestingly, they also included in their reference level guidance the amount of fluorography frames and also exposure times. For the two procedures a time of 7.5 minutes and 17 minutes and frame counts of 1250 and 1300 were suggested for CA and PTCA respectively.

In the same vein of work as that of Neofotistou *et al.* (30), Padovani *et al.* (63) set reference levels for European cardiac interventional procedures in 2008. They used patient information collected in nine European partner countries and evaluated close

to 2000 procedures. They divided cardiac cases in three groups, namely CA, PTCA and a combined group of electrophysiology procedures which included radiofrequency ablation and pacemakers. The DRLs were expressed as rounded 3<sup>rd</sup> quartile values and similar to Neofotistou *et al.* (30) included time and frames used.

The Padovani *et al.* (63) DRLs were calculated as 45, 85 and 35 Gy.cm<sup>2</sup> for CA, PTCA and the combined electrophysiology procedures respectively. The time was 6.5, 15.5 and 21 minutes for the 3 groups of procedures. The frames were only given for CA and PTCA as 700 and 1000. This showed a reduction from the Neofotistou *et al.* (30) proposal done five years earlier. They attribute this reduction in the DRLs as being a direct result of the reduced number of frames used on average for these procedures. This shows that a DRL establishment can lead to a dose reduction in populations.

In 2012 Miller *et al.* (64) proposed initial interventional cardiology reference levels for the United States. They used data from 171 facilities in 30 states in the United States, collected by centres participating in their Nationwide Evaluation of X-ray Trends (NEXT) survey. The procedures selected in this study included diagnostic cardiac catheterizations, PCI and combined diagnostic cardiac catheterization with PCI. They proposed 3 quartile DRLs of 83, 193 and 199 Gy.cm<sup>2</sup> respectively for diagnostic cardiac catheterization, PCI and the combined procedure.

These initial levels in the US are much higher than the levels proposed in Europe (63) and the authors strongly suggest that there is opportunity for improvement in US practice. Miller *et al.* (64) mentions that one possible reason for the high US levels is the relative absence of data suitable for reference level determination from the US national registry. (70) They conclude by stating that there is no doubt that continued

collection of data from US institutions will permit refinement of their initial levels and will promote dose optimization efforts.

## **2.4 DRLs in South Africa**

In the South African context limited publications mentioning DRLs exist and no full publications were found addressing interventional cardiology reference levels. There are some publications defining and proposing DRLs for general radiation procedures.

In 2009 Nyathi *et al.* (71) potential DRL's for common radiography projections, including chest, pelvis, abdomen, lumbar spine and thoracic spine. They used exposure information from 117 patients examined at the Charlotte Maxeke Johannesburg Academic Hospital (CMJAH). Their DRLs were established using the 3<sup>rd</sup> quartile entrance surface air kerma values that were derived. Potential DRLs were 0.1, 0.22, 2.98, 4.19, 5.3 and 3.28 mGy for Posterior-Anterior (PA) chest, lateral chest, Anterior-Posterior (AP) pelvis, AP abdomen, AP lumbar spine and AP thoracic spine. These levels compared favourably to similar work done in Brazil (72), Iran (73), United Kingdom (12) and the International Atomic Energy Agency (IAEA) (74).

The authors suggest that the lower reference levels may be because of the small scale of their project compared to the international multicentre surveys (74), which certainly have many more variables in equipment type, operator and radiographic

technique. This publication notes the lack of locally available DRLs in South Africa and proposed these be used as a starting point for general radiology. (71)

Engel-Hills & Hering (75) investigated the use of DAP values to calculate DRLs for barium enema procedures in the Western Cape of South Africa. Data collected for this study included a sample of 50 patients from three departments within the Western Cape Province public hospitals. The DRLs calculated were compared with international barium enema dose levels, specifically those of the United Kingdom. The third quartile of their distribution was calculated as  $84 \text{ Gy}\cdot\text{cm}^2$  which they proposed to be used as an initial reference level for South Africa. At the time median levels compared with those published in the United Kingdom showed that South Africa's median was slightly higher, with median doses of  $48 \text{ Gy}\cdot\text{cm}^2$  vs.  $41 \text{ Gy}\cdot\text{cm}^2$ .

Following this article of 2001, Engel-Hills *et al.* (76) published supplementary work on radiation protection in medical imaging in 2006. This work focuses on general radiation protection and the critical importance of dose measuring devices, like DAP meters, in radiology. They encourage practitioners to take into account the increase in demand of radiation protection, and to optimize the exposure of patients, health care practitioners and the public.

The theme of the 2007 South African Association of Physicists in Medicine and Biology (SAAPMB) congress was, "Diagnostic Reference Levels". This certainly shows support for the DRL principal among local medical physicists, but unfortunately, even today, there is still no national database of exposure information or DRLs. The 2007 SAAPMB congress had as invited speaker Dr Joel Gray who has been actively involved in the AAPM, ICRP, NRCP and IAEA committees for the development of DRLs worldwide. Dr. Gray introduced DRLs and the method used

from an American viewpoint using the Nationwide Evaluation of X-ray Trends (NEXT) survey at this congress. He presented results from this NEXT survey data analysis, indicating variations of more than 100 times on one projection across America. (77, 78)

During the SAAPMB 2007 congress Malan *et al.* (79) presented an audit of patient data from patients receiving vascular interventional radiology at the Universitas Hospital in Bloemfontein. This study included 1150 patients that had received various vascular procedures, including neurological, peripheral vascular, abdominal and thoracic investigations.

Malan *et al.* (79) showed the procedures recorded with the highest DAP readings were Four Vessel Angiography, Uterine Artery Embolization (UAE) and Endovascular Artery Repair (EVAR) procedures, which represented 121 of the total amount of procedures. The mean DAP values recorded for these three procedures were 126, 210 and 350 Gy.cm<sup>2</sup>. They calculated the mean DAP for all 1150 procedures as 54.1 Gy.cm<sup>2</sup>.

At the same congress, in 2007, Kotze *et al.* (80) presented research done on radiation doses in diagnostic radiology at Groote Schuur Hospital, situated in the Western Cape Province of South Africa. They measured entrance skin doses for a number of diagnostic examinations that included AP chest, lateral chest, AP abdomen, pelvis, AP cervical spine, AP thoracic spine, and AP lumbar spine. For these procedures average entrance surface values of 0.31, 1.64, 4, 4.1, 1.3, 3.1 and 4 mGy were recorded respectively. The authors conclude that it would be possible to develop reference levels for common examinations.

At the SAAPMB congress of 2015, Makosa & Conradie (81) presented, and published an abstract of, a dose audit performed at Universitas Academic Hospital in Bloemfontein. Exposure data was recorded for 2014 and DRLs were expressed as the 3<sup>rd</sup> quartile values. They benchmarked their local reference levels in interventional cardiology as Coronary Angiography (153 Gy.cm<sup>2</sup>), Pacemakers (43 Gy.cm<sup>2</sup>) and Transcatheter Aortic Valve Implantation (32 Gy.cm<sup>2</sup>)

The South African National Department of Health: Directorate Radiation Control license conditions (17) dictate that, *“the license holder shall: establish a program to ensure that the radiation dose administered to a patient for diagnostic purposes is optimized.”*

These licence conditions further states that the values of DAP readings shall be used for the purpose of optimization of fixed fluoroscopy interventional procedures. These licence conditions, although heavily debated in South Africa, create an opportunity for radiologists, radiographers and physicists alike to investigate radiation doses, optimize and possibly develop local DRL's. (82)

This literature review portrays an absence of locally available DRL's, some limitations in international DRL's and the statements in South African licensing conditions that emphasize the need for this study.

## **CHAPTER 3 METHODOLOGY**

### **3.1 Interventional Procedure Selection**

The X-ray machines identified to be used were all fixed fluoroscopy units used in cardiology, hybrid or vascular theatres housed in private hospitals in South Africa. The machine and operating theatre type naturally influenced the procedure selection. In total, 27 interventional radiology theatres were identified to be included. This included imaging equipment built by different equipment manufacturers, which mostly included commercially available interventional x-ray machines from the range that Siemens and Phillips offers.

Through consultation with the unit managers, radiographers, cardiologists and vascular surgeons, the most common procedures or procedure combinations were identified to form part of the study. Although some interventional radiology procedures were included, this study focused on cardiac diagnostic imaging and interventions. The cardiology focus was because that was the focus of most of the catheterization theatres included in this work.

Interventional radiology procedures across most disciplines can be broadly classified into diagnostic studies and interventions. (83) Typically diagnostic studies are for the purpose of diagnosing a problem or the extent thereof. Examples of diagnostic procedures are CA, Cerebral Angiography or Renal Angiography etc. The diagnostic procedure would normally be simpler and quicker than the intervention, which should result in diagnostic procedures having a lower radiation dose. Interventions normally follow after a diagnostic procedure, aiming to repair or improve the problem or function; examples of interventions are PTCA, Pacemaker Placement or

Radiofrequency Ablation, etc. The literature review indicated that in South Africa there is a lack of fluoroscopy DRLs for both diagnostic and interventional procedures; thus the procedure list aimed to include both classifications.

The first list of the most common procedures or procedure combinations identified to form part of the study is shown in Table 3.1.1(a). Each procedure or investigation was assigned a name, “also known as” name and detailed description. Annexure 8.2 shows the detailed descriptions of each procedure and Table 3.1.1 shows the names only. This description and “also known as” name was included to assist radiographers and theatre managers with data collection by clearly defining procedures types.

During the course of this study the list was expanded. In January 2013 an additional 10 procedures were included as this was requested by the clinical teams involved. The updated list, which included 24 procedures, is shown in Table 3.1.1(b).

Table 3.1.1: Procedure names for (a) the initial 14 procedures used in Jun – Dec 2012 and (b) the additional 10 procedures added in Jan 2013. Annexure 8.2 includes the detailed descriptions of each of these procedures.

(a) Initial procedures (Jun–Dec 2012)	(b) Additional procedures (Jan-Dec 2013)
Coronary Angiography	Cerebral Angiography + Interventions
Cerebral Angiography	Peripheral Angiography
Renal Angiography	Peripheral Interventions
CA + Angioplasty (Balloon)	CA + EPS

CA + Angioplasty (+ Stent)	CA + EPS + Ablation
Ablation (RF)	CA + LV + Angioplasty + 2 Stent
Ablation (RF + Robotic)	CA + LV + Angioplasty + 3 Stent
EPS	EVAR
CA + LV function	Permanent Catheters
CA + LV + Angioplasty (Balloon)	Paediatric Diagnostic Heart Caths
CA + LV + Angioplasty (+ Stent)	
Pacemaker (Permanent)	
Pacemaker (Bi Vent)	
TAVI	

*Coronary Angiography (CA), Radiofrequency (RF), Electrophysiology Study (EPS), Endovascular Artery Repair (EVAR), Trans Aortic Valve Implantation (TAVI)*

### 3.2 Data Collection

In April & May of 2012 the exposure data at four interventional theatres of the larger hospitals within the private hospital group were retrospectively reviewed. The purpose of this review was to set up the Microsoft Excel data collection sheets and templates to enable either radiographers or unit managers to submit their theatres' data easily, accurately and on time.

Figure 3.2.1 shows a screenshot of the data collection sheet issued to participating theatres. Theatres were instructed to include cases done from June 2012. The sheet had instructions and other information clearly indicated on the sidebar of the Microsoft Excel workbook. An additional worksheet which included the descriptions of procedures was added to this workbook. Annexure 8.2 lists these individual procedure descriptions.

**Patient Dose Optimization Program for Interventional Radiology (Data Sheet)**

Hospital: [REDACTED]  
 Lab: [REDACTED]  
 Data Collection Period Start date: 01 June 2012  
 & End date: 30 June 2012  
 Data Submission Date: 02 July 2012

	Procedure Performed	Exposure Time (Minutes)	DAP Reading (select unit)
1	Coronary Angiography		
2	Cerebral Angiography		
3	Renal Angiography		
4	CA + Angioplasty (Balloon)		
5	CA + Angioplasty (+ Stent)		
6	Ablation (RF)		
7	Ablation (RF + Robotic)		
8	EPS		
9	CA + LV function		
10	CA + LV + Angioplasty (Balloon)		
11	CA + LV + Angioplasty (+ Stent)		
12	Pacemaker (Permanent)		
13	Pacemaker (Bi Vent)		
14	TAVI		
15			
16			
17			
18			
19			
20			
21			
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23			
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30			

**AIM:**  
 The purpose of this program is to establish & monitor Diagnostic Reference Levels (DRLs) for the most common procedures performed in [REDACTED] interventional labs; aiming to optimize the dose required to perform these interventions.

**TAKE NOTE:**  
 This form must be submitted in electronic format! If this form is not submitted on or before the submission date, the data cannot be used as part of this study.

**INSTRUCTIONS:**

1. Ensure that the correct DAP units are selected for the unit, use the dropdown list. (Cell D11)
2. Only make an entry if the patient is of normal weight. (exclude all pediatric, or morbidly obese patients.)
3. Select the name of the procedure from the dropdown list under the "PROCEDURE" (Column B)
  - a) Only record the procedures if it appears on the dropdown list. If the procedure is not on the list it is not part of the study's selected for the program and may be excluded.
  - b) Only select "Coronary Angiography" if it was the only procedure performed.
  - c) Refer to "Procedure description" tab for more details on each procedure type.
4. Type in the Exposure Time (in minutes) next to the procedure under the "TIME" (Column C).
5. Type in the DAP meter reading in the "DAP reading" (Column D).
6. Column A is a number for the case submitted. This identifier is used for traceability for the lab and is not used as part of the study.

Figure 3.2.1: Screenshot of a section of the Data collection sheet issued in June 2012. The participating hospital group name has been removed.

In an attempt to minimize mistakes, the data collection sheets were locked for editing, except for the data required and the drop down lists that were used to assist with standardized capturing. The data capturing cycle was decided to be monthly. Time periods were clearly indicated on each collection sheet.

Each interventional theatre had two persons responsible for data capturing and submission. Training was given to unit managers and/or radiographers to ensure accurate data capturing. All procedures done that didn't fit one of the 24 procedure

description exactly were excluded from capturing. Paediatric cases were excluded except for Paediatric Diagnostic Heart Catheterization which was one of the 24 procedures investigated. The subsequent patient population captured included all cases done which conformed to one of the 24 procedure descriptions and excluded only paediatric patients and morbidly obese patients which were defined as having a Body Mass Index (BMI) of higher than 40.

Information to be collected included a procedure description, DAP and screening time. (65) The selection of these 27 interventional theatres housed equipment from various manufacturers, who expressed DAP in different units of measure; this was corrected for in the collection sheet, where all doses were converted to  $\text{Gy}\cdot\text{cm}^2$ .

### **3.3 Dose Area Product (DAP) Calibration**

A Dose Area Product (DAP) or Kerma Area Product (KAP) meter is normally installed in the collimator assembly, underneath the field shaping device of the fluoroscopy unit. The DAP meters used for this study all measure in units of dose (Gy) per area, but measurements are displayed in different units of  $\text{Gy}\cdot\text{cm}^2$ ,  $\text{mGy}\cdot\text{cm}^2$  or  $\mu\text{Gy}\cdot\text{cm}^2$ .

The International Atomic Energy Agency (IAEA) Technical Report Series number 457 (TRS457) (84) recognises that there is an increased need for patient dosimetry measurements in diagnostic and interventional radiology and that it is important to have traceability of these measurements. The accuracy of a DAP meter, as with any

ionisation chamber, may drift over time and routine cross-calibration or verification of calibration is necessary. (84)

The Institute of Physics and Engineering in Medicine Report Number 91 (IPEM 91) (85) recommends annual calibration or as per manufacturer specification. An annual calibration frequency regime has been widely applied by medical physicists and engineers in many countries. (86) The South African X-ray licensing requirements specify that DAP meter cross-calibration should be confirmed on acceptance to be within the manufacturer specification and at least annually thereafter. (17) In this study an annual calibration regime was followed as regulated in South Africa.

Crawley *et al.*, (86) also emphasizes this need for calibration and suggested that annual calibration may possibly be too infrequent for some types of DAP meters. They surveyed 41 DAP meters fitted to over and under-couch x-ray tubes for a period of five years to assess their long-term stability. Their results showed that 77% of the over-couch x-ray tube DAP meters were within 10% accuracy, whereas for the under-couch DAP meters only 50% were within 10% accuracy.

The IAEA TRS 457 (84) provides guidance for the calibration of DAP meters using a diagnostic ionization chamber and using another DAP meter, or reference DAP meter. Other authors (87, 88) have shown that using either a diagnostic chamber or reference DAP meter produce comparable results with similar uncertainties. Larsson *et al.* (89, 90) describes optimal calibration methods and deviations in the DAP calibration using various methods.

However, Hetland *et al.* (87) did note that the reference DAP meter method was susceptible to beam quality or energy response. They found up to a 20% difference in the DAP meter response for a range of five diagnostic radiation beam qualities

between 40 – 150 kV. When the energy range was reduced to 70 – 150 kV, this range improved to within 6% for most of the DAP meters evaluated.

In this work a diagnostic chamber was used to calibrate the field DAP meters, because it is accepted as an accurate method and because a reference DAP meter was not available to use for this purpose. The IAEA TRS 457 (84) further differentiates between an under and over-couch setup for calibration purposes.

Figure 3.3.1 shows a diagram of the calibration setup reproduced from the TRS 457 for both orientations.

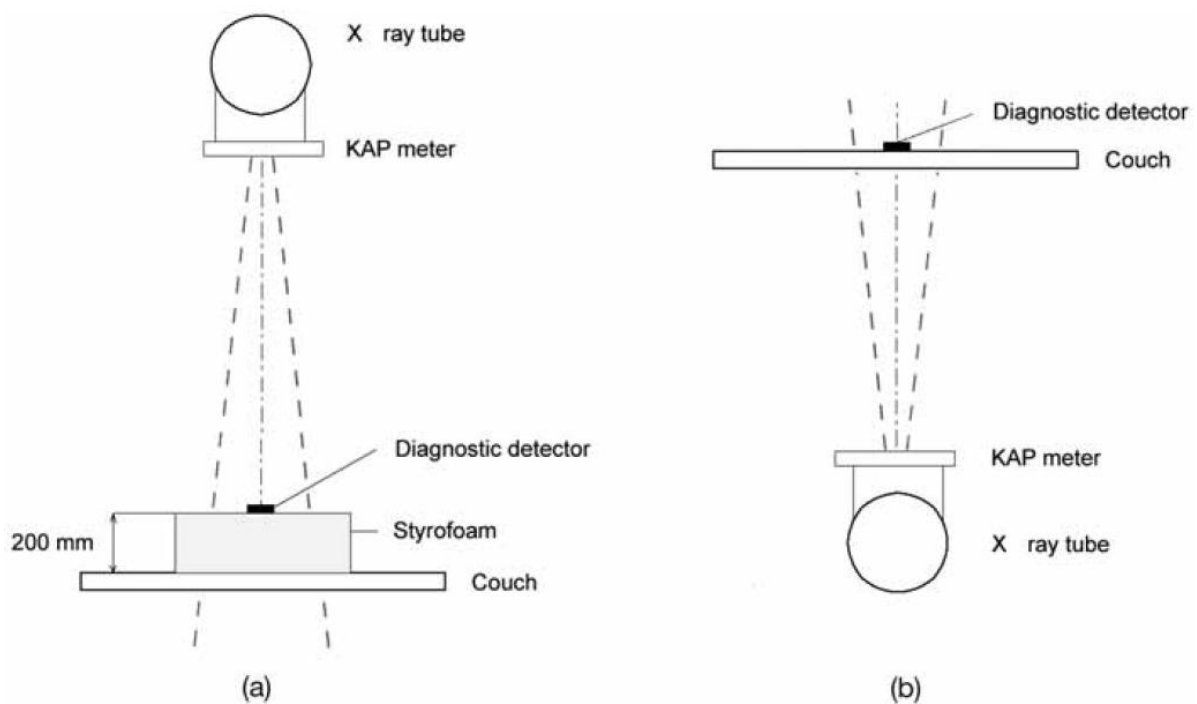


Figure 3.3.1: IAEA TRS 457 (84) DAP meter calibration setup for (a) over-couch installation and (b) under-couch installation. *Figure reproduced from the IAEA TRS 457 (84)*

Equation 3.3.1 is used in TRS 457 to calculate the calibration coefficient,  $N_{PKA,Q}$ . The readings from the chamber,  $M_Q^{ref}$ , and from the KAP meter,  $M_Q^{KAP}$ , are used. The nominal beam area is given by  $A_{nom}$ . In this equation 3.3.1, the factor  $N_{K,Q_0}^{ref}$  is the calibration coefficient for the reference dosimeter at beam quality  $Q_0$  and  $k_Q^{ref}$  corrects the reference dosimeter reading for the difference in response between beam qualities  $Q_0$  and  $Q$ .

$$N_{PKA,Q} = \frac{M_Q^{ref}}{M_Q^{KAP}} N_{K,Q_0}^{ref} k_Q^{ref} A_{nom} \quad \text{Equation 3.3.1(84)}$$

Martin *et al.* (91) evaluated the use of semiconductor chambers, like the Unfors/Raysafe Xi System (92) used in this work, for the purpose of diagnostic dosimetry measurements.

Martin *et al.* (91) found that, despite being directional, semiconductor systems showed small variations in energy response, because of energy compensation methods applied by incorporating several elements. These chambers were recommended for dose measurements at radiology x-ray energies, but the directionality was noted as excluding backscatter from measurement.

The Unfors/Raysafe Xi detector (92) used in this work employs multiple solid state detector elements to automatically determine the beam quality being measured and is able to eliminate the need for further beam quality correction in the diagnostic energy range.

This automatic correction is termed, by the supplier, the chamber's Active Compensation Technology (93) module. Figure 3.3.2 shows that the beam quality response of the Unfors/Raysafe detector, as a result of the active compensation technology, is not affected by changing incident beam energy or beam quality.

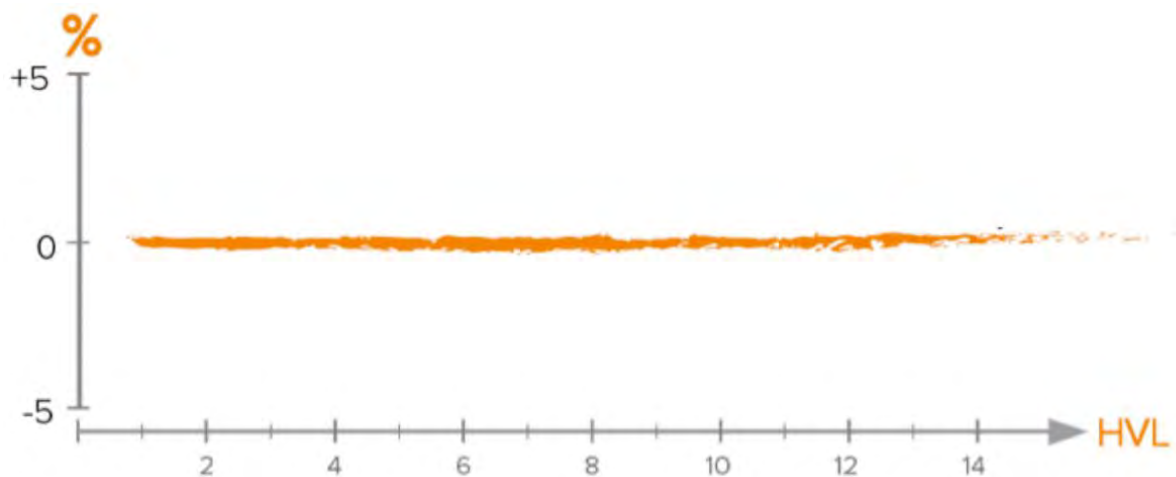


Figure 3.3.2: The beam quality response of the Unfors/Raysafe detector as a result of the active compensation technology used. *Image reproduced from the Raysafe website. (93)*

In 2008 Jankowski *et al.* (94) investigated a simple calibration method on 31 KAP meters installed on cardiac and interventional x-ray equipment from various manufacturers. They state that KAP meters measure the air kerma (K) integrated over beam area (A).

This is expressed as  $\int_A K_{c,air} dA$  by Jankowski. The simplified calibration method approximates the integral by measuring and multiplying the air kerma in the centre of a field with the known exposed area. This enabled them to calculate a KAP

calibration factor for each system. Their results show, taking into account random and systematic errors, an uncertainty of  $\pm 6\%$  at the 95% confidence interval using this simplified method. (94)

Toroi & Kosunen (95) state that a DAP calibration within a 7% uncertainty is acceptable and indicates a good calibration, and to achieve <5% uncertainty would be a very difficult task. They further note that even within a 10% uncertainty the calibration will sufficiently cover clinical radiation qualities used in fluoroscopy. Terini et al. (88) showed a 5% variance using a reference DAP meter technique and a 3.5% when using a diagnostic chamber for calibration.

The cross-calibration method utilised in this work is based on the methods of cross calibration for DAP/KAP meters explained in the TRS 457 (84) and on the infield simplification used by Jankowski *et al.*, (94) described earlier in this chapter. Each medical physicist was responsible for the calibration of the x-ray machines within their regions and was supplied with a calibration procedure and calibrated Unfors/Raysafe (92) dose meter. The equation used to calculate the calibration coefficient is shown in equation 3.3.2.

This equation expresses the simplified method used by Jankowski *et al.* (94) in the format as given by the IAEA TRS report 457. Equation 3.3.2 takes into account the Active Compensation Technology (93) used in the Unfors/Raysafe detectors, which makes the measurement device not sensitive to energy/beam quality changes in the diagnostic energy range. This enables the removal of detector beam quality corrections,  $N_{K,Q_0}^{ref}$  and  $k_Q^{ref}$ , as stated in equation 3.3.1. The terms used in this formula are as described for equation 3.3.1.

$$N_{P_{KA,Q}} = \frac{M_Q^{ref}}{M_Q^{KAP}} A_{nom} \quad \text{Equation 3.3.2}$$

In this work all DAP meters were calibrated before the start of the data collection and periodic cross-calibration was performed as required during its course. In cases where calibration was not possible, a correction factor was used to correct the measured DAP value for each procedure.

Dose measurements were done using four sets of Unfors/Raysafe Xi range (92) of measuring devices, designed to perform measurements in diagnostic beam qualities. These dose meters were all calibrated with traceable calibration certificates from laboratories with ISO/IEC 17025 accreditation (96).

Two methods were followed to calibrate (and /or verify) the DAP meters. A cross-calibration or verification of a DAP meter requires the accurate field size and a dose measurement at the same Source to Surface Distance (SSD). Which technique was used was at the discretion of the medical physicist, depending on the type of interventional machine, its radiation field shaping capabilities and the type of DAP chamber.

1. The first DAP calibration method was used when interventional machines have limited field shaping capabilities as often seen on older equipment using image intensifier fluoroscopy technology. This procedure is also accurate on most machine types and requires the use of a fluorescent screen, copper sheet and a calibrated dose meter. The interventional unit gantry is rotated to 90 degrees and a 2 mm

copper sheet is placed on the intensifier or flat panel (image detector). A diagram of this setup is shown in figure 3.3.3.

The purpose of the copper is to increase the X-ray tube output which decreases the uncertainty in measurement and improves visualization of the X-ray field on the fluorescent screen. The fluorescent screen is placed between the X-ray tube and copper plate. When this setup is exposed using fluoroscopy in a room with low background light, the radiation field size is seen on the fluorescent screen as visible light which enables the measurement of the radiation field dimensions using a ruler. The radiation field is normally either square or rectangular in shape and the size of area can be calculated by multiplying together the length and width of the field sides. The calibrated Unfors / Raysafe dose meter is positioned directly on the fluorescent screen in the centre of the field, to measure a point dose in Gray (Gy). The TRS457 (84) notes that a 200 mm distance is recommended between the object and the dosimeter to avoid possible backscatter radiation. The Unfors / Raysafe Xi detector used for measurements is suitably shielded for backscatter (91, 92) and may be placed directly on top of the attenuating material. The dosimeter is positioned in the beam centre and the field collimated around the chamber.

2. The second method is used when interventional machines have good field shaping capabilities, as seen on most flat panel detector technology, where the collimator can be easily adjusted to conform to the visualised object's dimensions. The precise square field size at the measuring point is important. (e.g. 10 cm X 10 cm) This field size can be obtained by using the Normi 4 Flu phantom grid and using fluoroscopy to set the field size. This field size is given in units of  $\text{cm}^2$ . No magnification should be set when determining the field size.

After the field size has been set, either the DAP meter must be reset or the accumulated reading must be noted for subtraction when the calibration verification calculation is performed. 2 mm copper must be added on the image intensifier to increase the tube output, which will decrease the uncertainty in the dose measurement. The dose is measured by exposing the setup continuously for approximately 20 - 30 seconds.

The DAP is calculated by multiplication of the squared field size and the point dose. The result is in a value that is the product of dose and area. This is divided by the time to obtain the unit as dose X area per time. The displayed DAP reading from the meter should also be divided by the time and compared to the measured DAP reading.

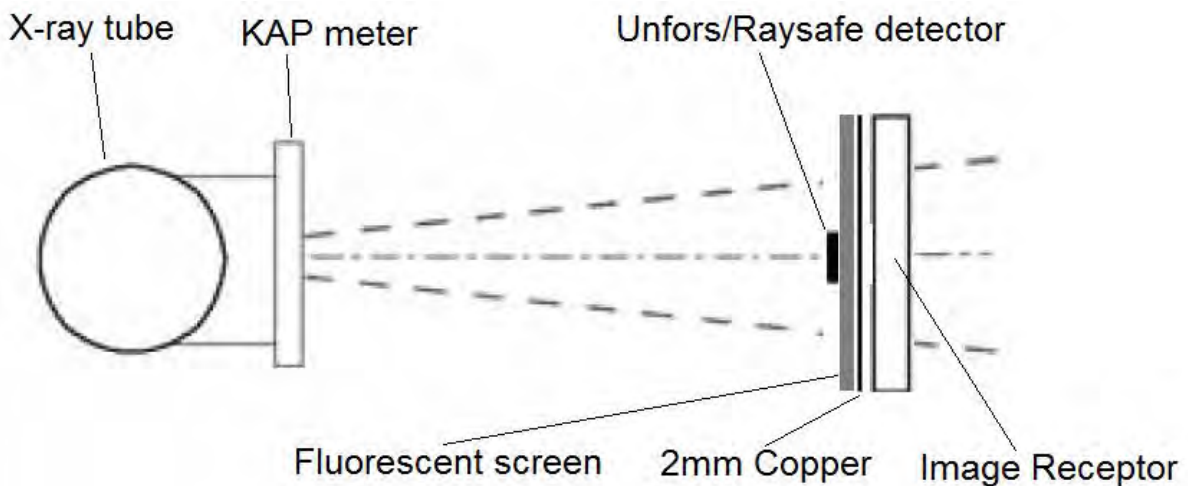


Figure 3.3.3: Diagram illustrating the DAP meter calibration setup.

### 3.4 DRL Calculation and Statistics

The time period for this study stretched from June 2012 to December 2013, which was split into six quarters. Quarter 3 2012 (Q3 2012) included data from June-September 2012 and Quarter 4 2012 (Q4 2012) included October-December 2012.

In a similar fashion 2013 was split up into four quarters, namely, January-March (Q1 2013), April-June (Q2 2013), July-September (Q3 2013) and October-December (Q4 2013).

The DAP readings recorded at the imaging modalities were used as primary measurements and averages and DRLs ( $\text{Gy}\cdot\text{cm}^2$ ) were calculated from these. The exposure data received is best presented when using a histogram curve, which clearly shows the population frequency in different DAP ( $\text{Gy}\cdot\text{cm}^2$ ) bins. This is consistent with other authors using similar methods to evaluate the distribution. (64)

There are different ways to define reference levels; in this study the 3<sup>rd</sup> quartile of the distribution was used, which was calculated for each type of procedure and for each quarter. The 3<sup>rd</sup> quartile DRL simplifies comparisons with work published from other countries. (97, 98) Further statistical analysis of the DAP distribution included calculation of the 1<sup>st</sup> quartile, inter-quartile range and the standard deviation for each procedure.

### **3.5 Optimization & Feedback**

The term optimization and more specifically dose optimization goes alongside the consideration of acceptable or sufficient clinical image quality during a diagnostic procedure or intervention. Good radiology techniques aim to provide the doctor with acceptable image quality depending on the type of exam and it considers radiation dose when doing this. Acceptable image quality describes what information is required as a minimum for the doctor to diagnose accurately or to perform a procedure safely. Conversely excessive image quality describes images where surplus information is present that is not necessary for the type of procedure. Excessive image quality can lead to unnecessarily high radiation doses to patients and should be avoided.

When the term optimization is used in this work it aims to find the balance between acceptable image quality and radiation dose. When optimization is used to describe changes to the radiographic technique it can be assumed that sufficient image quality was the goal and that the technique changes did not result in an unacceptable loss of image quality.

Feedback from the data collection process and the optimization attempt was considered very important throughout the period of data collection, especially feedback to participants regarding possible optimization or lack thereof. The method of feedback was decided to be a newsletter that was sent to all stakeholders in the private sector interventional theatres that participated.

The stakeholders included, among others, theatre unit managers, registered nurses, radiographers, medical physicists, hospital safety officers, hospital administrators,

specialist doctors and members of the private hospital board of directors. The information shared with stakeholders included their mean DAP values for common procedure types and comparisons to their neighbouring hospitals, as well as comparisons to published international references levels from Europe and elsewhere. (63, 64, 74) Other authors have shown that complex technique investigations, adjustment and knowledge of a possible high dose used have shown to improve dose usage. (23, 99)

In South African interventional theatres the radiographer is considered the trained specialist in radiographic technique and safety. The cardiology scope of practice does not allow x-ray unit operation without a radiographer present and for these labs that is the status quo. The normal practice in the labs partaking in this study allows screening by either the radiographer or specialist doctor, depending on the practitioner's preference. Generally the radiographer will set up and control the technique setting, whilst the specialist engages fluoroscopy when required. Arthur *et al.* (100) showed that techniques where cardiologists engage the fluoroscopy exposure may reduce dose compared to when radiographers engage the fluoroscopy exposure on instruction from the specialist doctor. The decision of who has their foot on the fluoroscopy pedal and whether that impacts dose was not assessed during this work.

It was a conscious decision to share hospital mean values with them in these newsletters, and not the 3<sup>rd</sup> quartile DRLs, considering that dose optimization was the goal.

During the preliminary session of the SAAPMB 2007 congress, Dr Joel Gray said, "*I am uncomfortable if I see some of the reference levels being published and I am*

*uncomfortable seeing the levels published by the AAPM. I know we can be much, much better than these levels. Where should we be in terms of dose? From what I have seen, if you have good medical physics support at your facility, you should be operating at less than 50 % of the reference levels. Think about that, it means you should be operating below the median exposure. That doesn't make sense. How can everyone be below the mean level? Simply because the reference values and average values are too high to start with. I am challenging you to look at the 50 % of the reference level as the target.” (77)*

Gray then concludes this preliminary session on the how and why of reference levels by saying, *“First and foremost, we have to look at optimized image quality and dose. Again my challenge to you, let's look at the 50 % DRL as the goal for our own departments.” (77)*

The optimization method used in this work, writing educational newsletters as feedback and disclosing the 50% DRL to participants, were done taking into consideration that our doses were high and had the aim of optimization in mind.

The communication letters were aimed to educate, encourage and enable interventional theatres to track their performance and possible optimization or lack thereof. Where high doses frequently occurred the focus was to distribute the IAEA radiation protection posters (101) and provide radiation protection training to staff.

It was realised that optimization may possibly require funding, if equipment upgrading or replacement were to be identified as the likely cause of centres exceeding reference levels. This was the main reason why hospital administrators and members of the board of directors were included in the communication.

It is noteworthy to mention that, during this period of DRL data collection and optimization, improvements were made to the incident management system. These improvements defined and quantified possible radiation incidents for individual patients when there was a likelihood of exceeding the threshold dose for skin erythema. These incident dose levels are by definition doses to individuals and not that of populations or groups of patients as found in the description of the DRL. Considering the large variability in complexity of interventional fluoroscopy procedures and the resulting radiation dose it is likely that theatres with optimized techniques may exceed these incident levels. These incident levels are for individual patients and should not be confused with DRLs.

Trianni *et al.* (102) proposed that investigation levels be set as low as  $140 \text{ Gy.cm}^2$  for cardiac cases. The IAEA radiation incident management system Safety in Radiological Procedures (SAFRAD) (103) indicates  $500 \text{ Gy.cm}^2$  as an investigation level. Neofotistou *et al.* (30) proposed a DAP skin reaction investigation level of  $300 \text{ Gy.cm}^2$  for interventional cardiology procedures as this could likely cause a skin reaction.

For this work fluoroscopic patient doses exceeding  $300 \text{ Gy.cm}^2$  were required to be reported for handling by the responsible medical physicist as an incident dose level. (104) This level is lower than that proposed by the IAEA, but considering the smaller field sizes often used during cardiac procedures this was considered a more suitable investigation level.

The incidents were graded depending on possible severity of the resulting skin reaction and were handled either by electronic correspondence or site visits. The incident grading was further used to guide the responsible physicist in management

and peak skin dose estimation. These incident reporting requirements reinforced the same radiation protection principles as the radiation dose optimization system.

### **3.6 Null Hypothesis**

The research question introduced in this work has two parts. Firstly, *“Are radiation doses used in South African private healthcare interventional laboratories high compared to those published internationally”* and secondly, *“will establishing dose reference levels optimize the doses used?”*

The null hypothesis will also have two parts. Firstly, to establish whether the DRL calculated per procedure is significantly higher than DRLs published internationally. The literature review portrayed some variation in published doses for the different procedures. The mean and standard deviation are sufficient to evaluate if South African DRLs compare well to international levels. If the South African DRLs fall within a range of the international DRL mean ( $\pm 1$  SD), then this should prove that local reference levels are not high in comparison. If South African doses fall outside, or are higher than, the range of international DRLs mean ( $\pm 1$  SD) this would indicate that local doses are elevated compared to international levels. This is the alternative hypothesis for the first part of the research question.

The second part of the proposed null hypothesis ( $H_0$ ) attempts to evaluate if there was optimization of radiation usage. Has the DRL improved with sufficient degree of statistical significance to prove there was dose optimization?

Equation 3.6.1 formulates the null hypothesis. The symbols  $\mu_1$  and  $\mu_2$  represents the 2012 Q3 (baseline) and 2013 Q4 (last quarter) DAP distributions respectively.

$$H_0: \mu_1 = \mu_2$$

*Equation 3.6.1*

If the null hypothesis is proven correct, it affirms that an insufficient degree of statistical evidence exist to support the relevance of differences in the means of  $\mu_1$  and  $\mu_2$ . Affirmation of the null hypothesis will mean no optimization can be proven. If the null hypothesis is rejected the alternative hypothesis ( $H_1$ ) , expressed in equation 3.6.2, stands.

$$H_1: \mu_1 \neq \mu_2$$

*Equation 3.6.2*

If the alternative hypothesis stands it affirms that a sufficient degree of statistical evidence exist to support the relevance of differences in the means of  $\mu_1$  and  $\mu_2$ . Affirmation of the alternative hypothesis, or rejection of the null hypothesis, will mean that optimization was proven.

The aim of optimization is to lower doses and improve the DRL over time. It is sensible to include a degree of measure in the null hypothesis to support the amount of optimization realised. The null hypothesis for the optimization part of the research question is formulated as equation 3.6.3, where  $M_1$  is the  $\mu_1$  mean DAP reading and  $M_2$  is the  $\mu_2$  mean DAP reading.

Equation 3.6.4 represents the alternative hypothesis. Using this will enable the acceptance or rejection of possible optimization measured for each procedure type as the differences of means.

$$H_0: \mu_1 - \mu_2 = (M_1 - M_2) = 0 \quad \text{Equation 3.6.3}$$

$$H_1: \mu_1 - \mu_2 = (M_1 - M_2) \neq 0 \quad \text{Equation 3.6.4}$$

Fagerland *et al.* (105) found that the most common approach to test the null hypothesis in medical research is the statistical independent samples t-test. They (105) add that it is an appropriate test if the distribution under evaluation follows a normal distribution curve or Gaussian distribution. This test is used when attempting to evaluate a hypothesis using the significance of differences in means acquired from normally distributed populations of data for two independent groups.

The literature review showed that it can be expected, that the distribution of DAP readings will likely have a positively skewed shape. (64) This is unfortunate because the statistical analysis of the distributions using independent samples t-test requires the data to have a normal distribution. (105)

This problem of non-normality of a distribution has been noticed by various authors (106-109) across the medical field. One solution to overcome the non-normality is using the  $\text{Log}_{10}$  of the population values before statistical analysis. (106-109) The DRL dataset is sufficiently large to allow some degree of freedom in suitability of the t-test and if the  $\text{Log}_{10}$  of the DAP distributions present as a normal distribution, then the t-test is appropriate to evaluate the hypothesis. Aroua *et al.* (97), applied this

method of using the  $\text{Log}_{10}$  in their advice for setting up DRLs at a national level in Switzerland for a variety of radiographic procedures.

Middleton (110) proposed that the degree of normality in the distribution, used to assess the aptness of the t-test, can be evaluated using a normal distribution probability graph. If the normal distribution probability graph can be adequately fitted using a linear equation, then the appropriateness of the t-test for the sample is justified. (110)

This method will be used to evaluate, firstly, if the  $\text{Log}_{10}$  of the distribution indicates normality and then, secondly, apply the t-test for evaluation of the null hypothesis.

## CHAPTER 4 RESULTS

### 4.1 DAP Calibration

During the course of 2012 the calibration of each DAP meter installed at the 27 participating x-ray units was verified by the responsible medical physicist in each region. This resulted in the initial calibration factors used. The initial factors are shown in Table 4.1.1 in the column Q3 2012.

As the programme progressed DAP calibrations were done as required for the purpose of annual quality control or in the event of major repair or replacement of a machine. The calibration factors for the other quarters, as applicable, are shown in columns Q4 2012 – Q4 2013. Machine number 22 was replaced during Q1 of 2013.

Table 4.1.1: DAP calibration factors used to correct data received from each lab.

X-ray	Q3	Q4	Q1	Q2	Q3	Q4
Unit	2012	2012	2013	2013	2013	2013
1	1.36	---	---	1.32	---	---
2	0.99	---	0.98	---	---	---
3	0.95	---	---	1.04	---	---
4	0.88	---	---	---	1.00	---
5	1.09	1.10	---	---	---	---
6	0.97	0.91	---	0.94	---	---
7	1.00	0.86	---	---	---	0.85
8	1.18	---	---	1.18	---	---
9	1.09	0.98	---	---	---	---
10	0.98	1.09	---	---	1.10	---
11	1.01	0.97	---	---	---	---

12	1.14	1.10	---	---	---	---
13	0.93	---	---	---	0.91	---
14	0.92	---	---	---	0.90	---
15	1.02	---	---	---	1.00	---
16	1.14	---	---	---	---	1.12
17	1.02	---	---	---	0.97	---
18	0.94	---	0.95	---	---	---
19	1.18	---	---	---	1.18	---
20	1.05	---	---	---	1.06	---
21	0.95	1.01	---	---	---	---
22	0.89	---	0.96*	---	---	---
23	1.05	---	---	---	0.98	---
24	1.00	1.10	---	---	---	---
25	0.88	1.00	---	---	---	---
26	0.89	0.83	---	---	---	---
27	1.10	---	---	---	1.11	---

\* (Replaced Unit)    --- (No change)

## 4.2 Data Dissemination

Patient DAP data was recorded in 6 quarters which resulted in a total of 20415 procedures. Each of the 27 theatres was assigned a random number for purposes of anonymity which remained unchanged in the results and discussion sections. The approximate geographical distribution of participating theatres is shown in Figure 4.2.1.

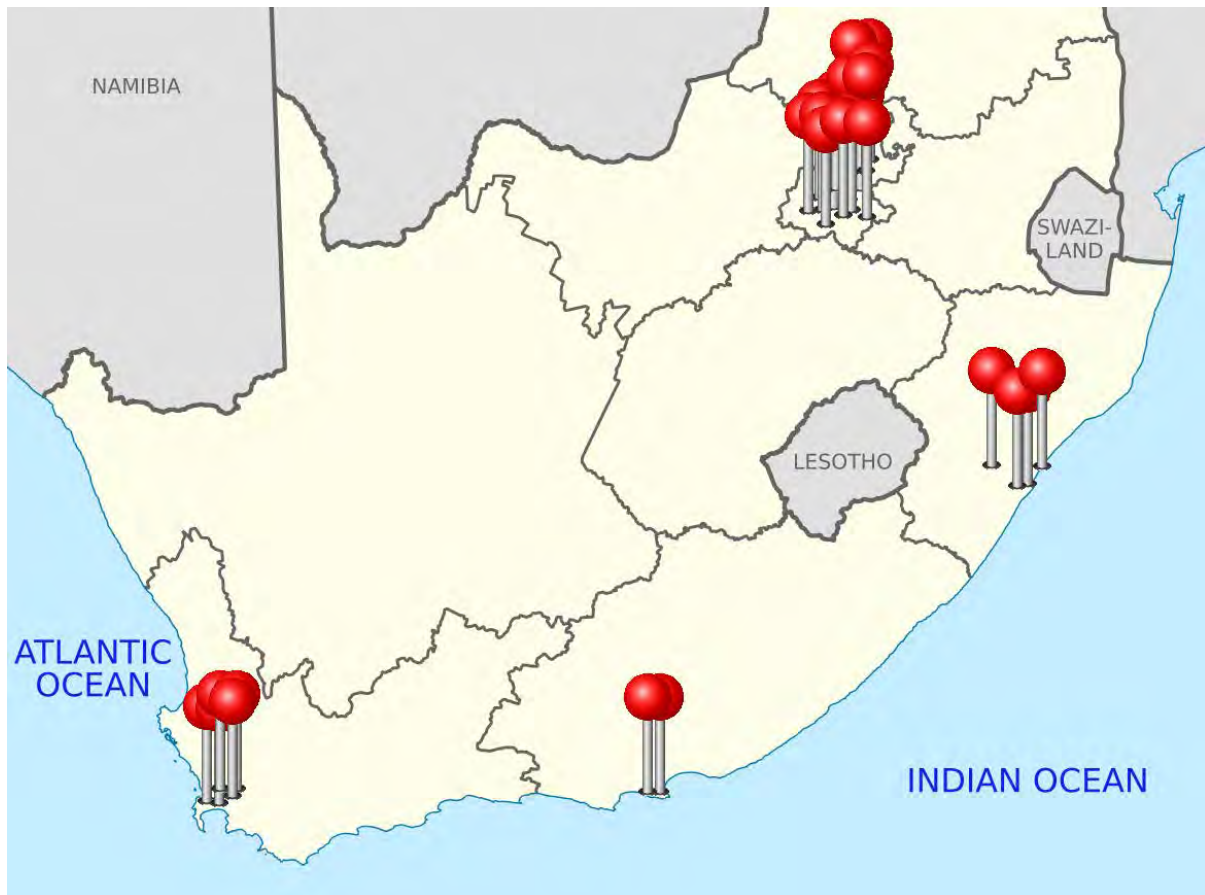


Figure 4.2.1: A map of South Africa showing the approximate position of the 27 interventional theatres included in this study. The red markers indicate the approximate position of each theatre. This illustration is an edited version of online content. (111)

Table 4.2.1 shows all the data recorded for each procedure type and includes the mean DAP value calculated per quarter. The procedures with a high incidence were CA, CA + LV, CA + PTCA + 1 Stent, PPM, PPM Biventricular and Radiofrequency Ablation. These procedures accounted for 76% of the total amount recorded and are highlighted in bold in Table 4.2.1. CA accounted for 3911 cases, CA + LV for 7547 cases, CA + PTCA + 1 Stent for 1885 cases, PPM for 1175 cases, Biventricular PPM for 280 cases and Radiofrequency Ablation for 675 cases respectively.

It was decided to investigate, in detail, these 6 most common procedures (2 diagnostic, 4 interventions) for the purpose of this thesis. Furthermore it was decided that because dose is the vital parameter featuring in both the aim and hypothesis of this work and because of the large amount of information in this dataset that the time parameter would not be further analysed. The literature review showed many studies referring to time, but the majority of authors found dose only to be sufficient which supports this decision. The detailed results for these six procedures are shown in subsections 4.2.1 – 4.2.6. Each of these subsections comprises of a table and two types of graphs explained below:

1. Tables 4.2.1-6.1 introduces each subsection and includes the mean, 1<sup>st</sup> quartile, 3<sup>rd</sup> quartile, standard deviation and inter-quartile range for each subsequent procedure and for every quarter.
2. Figures 4.2.1-6.1 (a-f) shows the data distribution for the six most common procedures displayed in a histogram each per quarter. All DAP values greater than 300 Gy.cm<sup>2</sup> were binned in to the 300 Gy.cm<sup>2</sup> bin. It is also quite clear from the histograms that the data is skewed and does not follow a normal distribution.
3. Figures 4.2.1-6.2 (a-b), Figures 4.2.1-6.3 (c-d) and Figures 4.2.1-6.4 (e-f) displays the mean DAP values, for the six studies selected, for each hospital and for every quarter.

Table 4.2.1: List of all procedures recorded and mean DAP values calculated for the different quarters ranging from Q3 2012 – Q4 2013. The mean DAP is expressed in units of Gy.cm<sup>2</sup>.

	Q3 2012		Q4 2012		Q1 2013		Q2 2013		Q3 2013		Q4 2013	
	n	Mean DAP	n	Mean DAP	n	Mean DAP	n	Mean DAP	n	Mean DAP	n	Mean DAP
<b>CA</b>	<b>676</b>	<b>61</b>	<b>608</b>	<b>45</b>	<b>626</b>	<b>48</b>	<b>704</b>	<b>44</b>	<b>775</b>	<b>49</b>	<b>522</b>	<b>47</b>
Cerebral Angiogram	54	120	28	95	15	192	18	163	43	123	21	137
Renal Angiogram	30	114	45	77	39	61	23	107	14	83	16	100
Peripheral Angiogram	-	-	72	110	46	83	73	75	62	64	19	52
CA + PTCA	60	153	70	135	38	123	32	110	41	132	49	171
<b>CA + PTCA + 1 Stent</b>	<b>496</b>	<b>147</b>	<b>264</b>	<b>118</b>	<b>267</b>	<b>130</b>	<b>359</b>	<b>131</b>	<b>314</b>	<b>129</b>	<b>185</b>	<b>137</b>
Cerebral Angio & Intervention	-	-	-	-	17	179	11	173	24	210	35	149
Peripheral Intervention	-	-	-	-	71	151	130	126	137	103	112	83
<b>Ablation</b>	<b>183</b>	<b>85</b>	<b>98</b>	<b>79</b>	<b>93</b>	<b>60</b>	<b>115</b>	<b>56</b>	<b>130</b>	<b>54</b>	<b>56</b>	<b>48</b>
Ablation + Robotic	49	77	34	49	34	56	37	50	27	58	-	-
EPS	80	25	-	-	20	15	17	19	41	7	12	6
CA + EPS	-	-	12	23	4	38	2	65	7	67	8	54
CA + EPS + Ablation	-	-	11	98	5	185	7	82	12	135	5	138
<b>CA + LV Function</b>	<b>1548</b>	<b>65</b>	<b>1207</b>	<b>58</b>	<b>1308</b>	<b>49</b>	<b>1461</b>	<b>51</b>	<b>1205</b>	<b>58</b>	<b>818</b>	<b>51</b>
CA + LV + PTCA	44	131	54	123	56	146	64	143	62	141	30	128
CA + LV + PTCA + 1Stent *	475*	153*	223	134	267	144	359	142	316	129	81	131
CA + LV + PTCA + 2Stent *	-	-	64	140	101	152	112	170	117	183	56	145
CA + LV + PTCA + 3Stent *	-	-	26	202	36	182	38	277	45	204	11	148
<b>PPM</b>	<b>284</b>	<b>37</b>	<b>182</b>	<b>48</b>	<b>214</b>	<b>33</b>	<b>204</b>	<b>33</b>	<b>175</b>	<b>36</b>	<b>116</b>	<b>29</b>
<b>Bi Vent</b>	<b>84</b>	<b>135</b>	<b>53</b>	<b>95</b>	<b>43</b>	<b>108</b>	<b>44</b>	<b>160</b>	<b>30</b>	<b>156</b>	<b>26</b>	<b>107</b>
TAVI	4	105	2	412	7	633	2	43	4	106	7	152
EVAR	-	-	-	-	17	704	20	849	8	375	7	515
Permanent Catheters	-	-	-	-	38	8	52	18	54	10	31	44
Pediatric L&R heart Caths	-	-	-	-	33	9	67	17	43	23	40	17

\* Name changed from LV & Stent for Q3 2012 to CA+LV+PTCA+Stent 1/2/3

## 4.2.1 Coronary Angiography

Table 4.2.1.1: The DAP readings recorded for CA displayed and analyzed for each quarter. The total number for procedures recorded for all six quarters was 3911. Indicated in bold is the baseline DRL calculated for quarter Q3 2012 as  $65.9 \text{ Gy.cm}^2$  and the DRL calculated in Q4 2013 is  $57.1 \text{ Gy.cm}^2$ . The amount of procedures is indicated as (*n*) and the standard deviation and inter-quartile ranges for each quarter are also shown.

CA	2012 Q3	2012 Q4	2013 Q1	2013 Q2	2013 Q3	2013 Q4
<i>n</i>	676	608	626	704	775	522
Average ( $\text{Gy.cm}^2$ )	60.6	45.1	47.9	44.0	49.0	46.8
1 <sup>st</sup> Quartile ( $\text{Gy.cm}^2$ )	23.1	16.8	17.9	21.44	21.7	20.9
3 <sup>rd</sup> Quartile ( $\text{Gy.cm}^2$ )	<b>65.9</b>	56	63.7	52.6	57.6	<b>57.1</b>
Inter-quartile range	42.8	39.1	45.8	31.2	35.9	36.2
Standard deviation	75.8	54.5	53.5	40.6	49.5	47.9

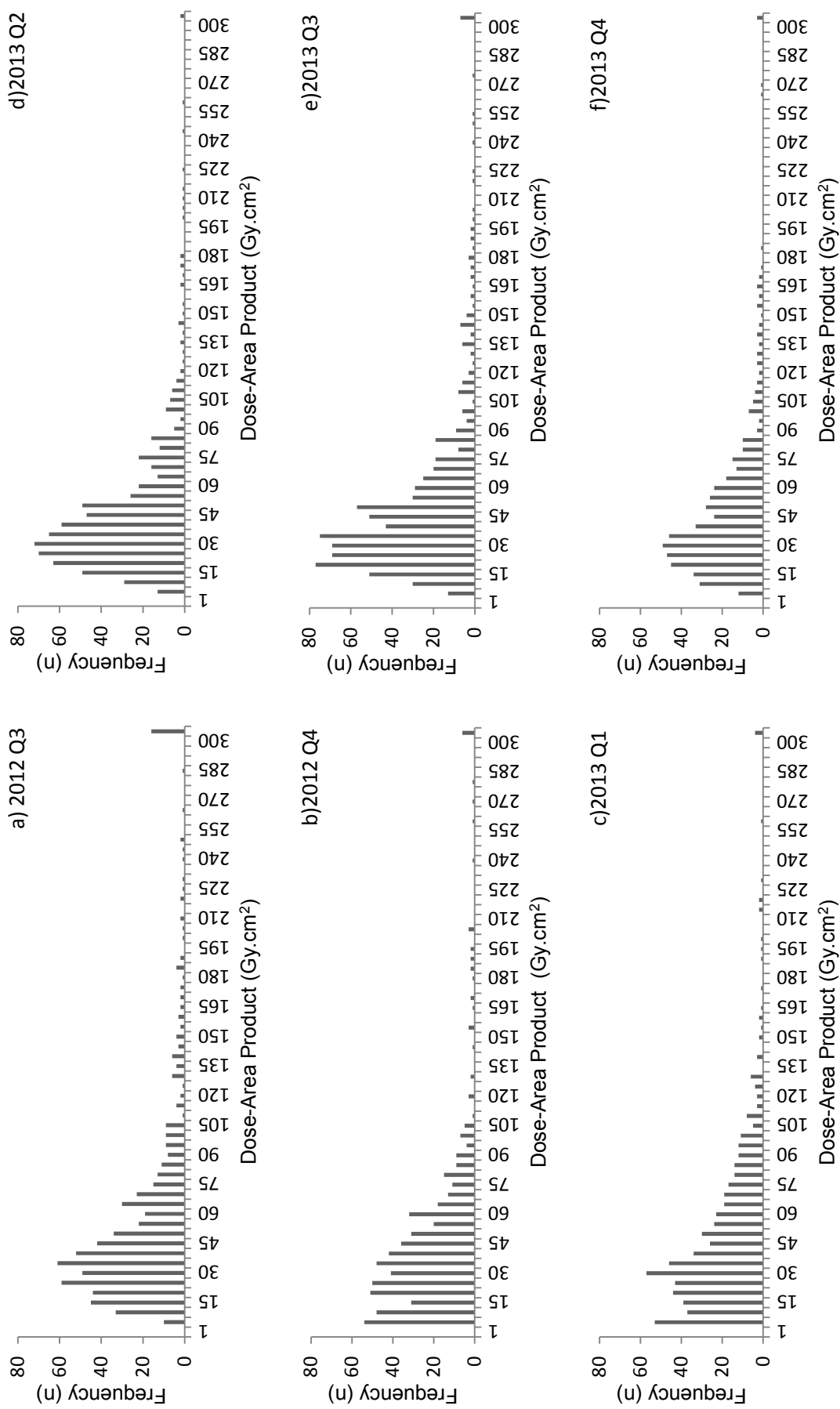


Figure 4.2.1.1 (a-f): Histograms of CA DAP readings displayed for quarter (a) 2012 Q3, (b) 2012 Q4, (c) 2013 Q1, (d) 2013 Q2, (e) 2013 Q3 and (f) 2013 Q4. The frequency (n) shows the amount of procedures recorded at different DAP levels (Gy.cm<sup>2</sup>).

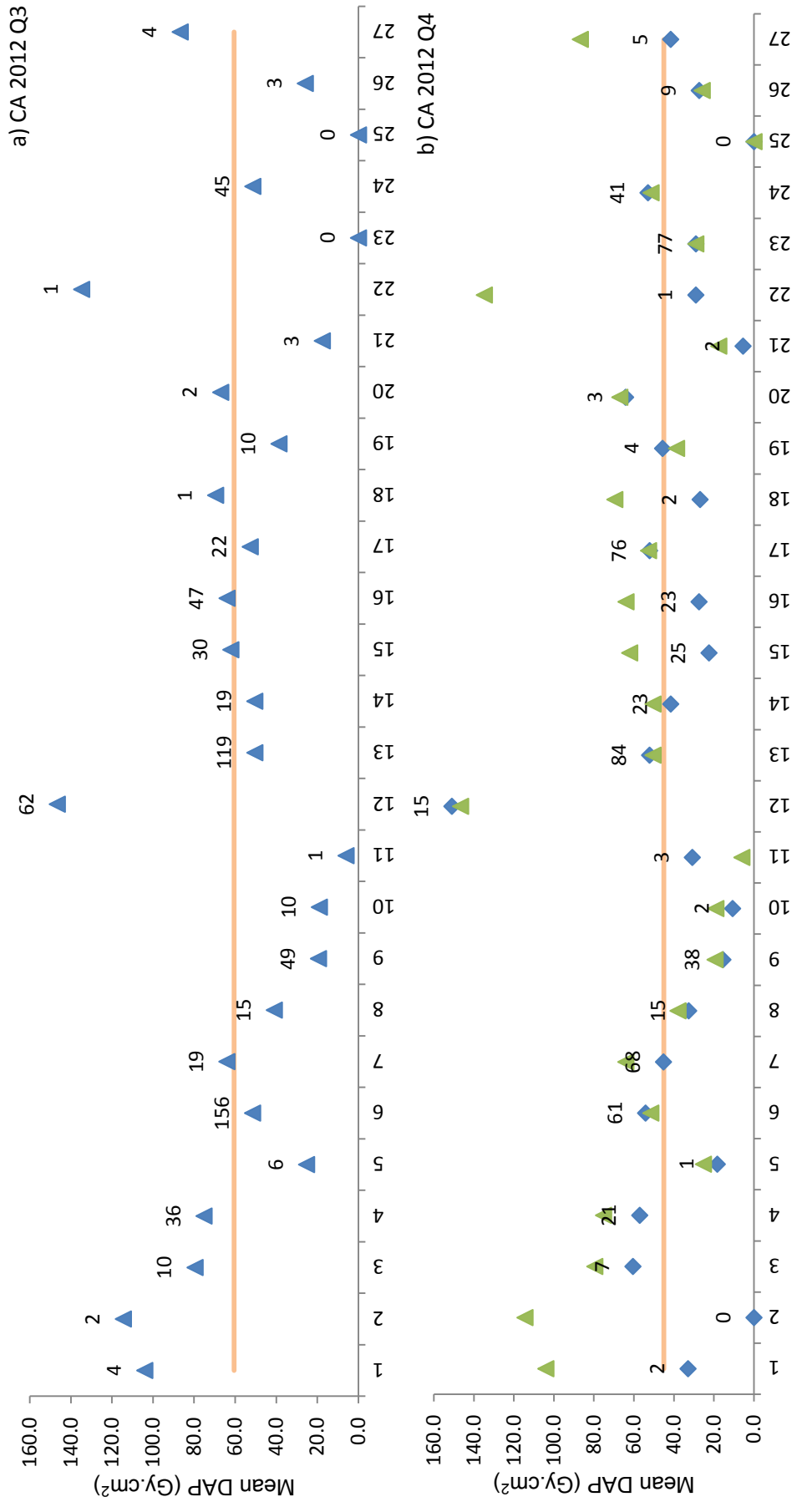


Figure 4.2.1.2 (a-b): Mean CA DAP readings displayed per theatre (x-axis) as recorded for (a) 2012 Q3 and (b) 2012 Q4. The triangles (▲) indicate baseline values recorded in Q3 2012 and the diamonds (◆) indicate readings for the respective period. The data labels indicate, per theatre, the number of cases recorded. The horizontal line represents the mean DAP for all cases.

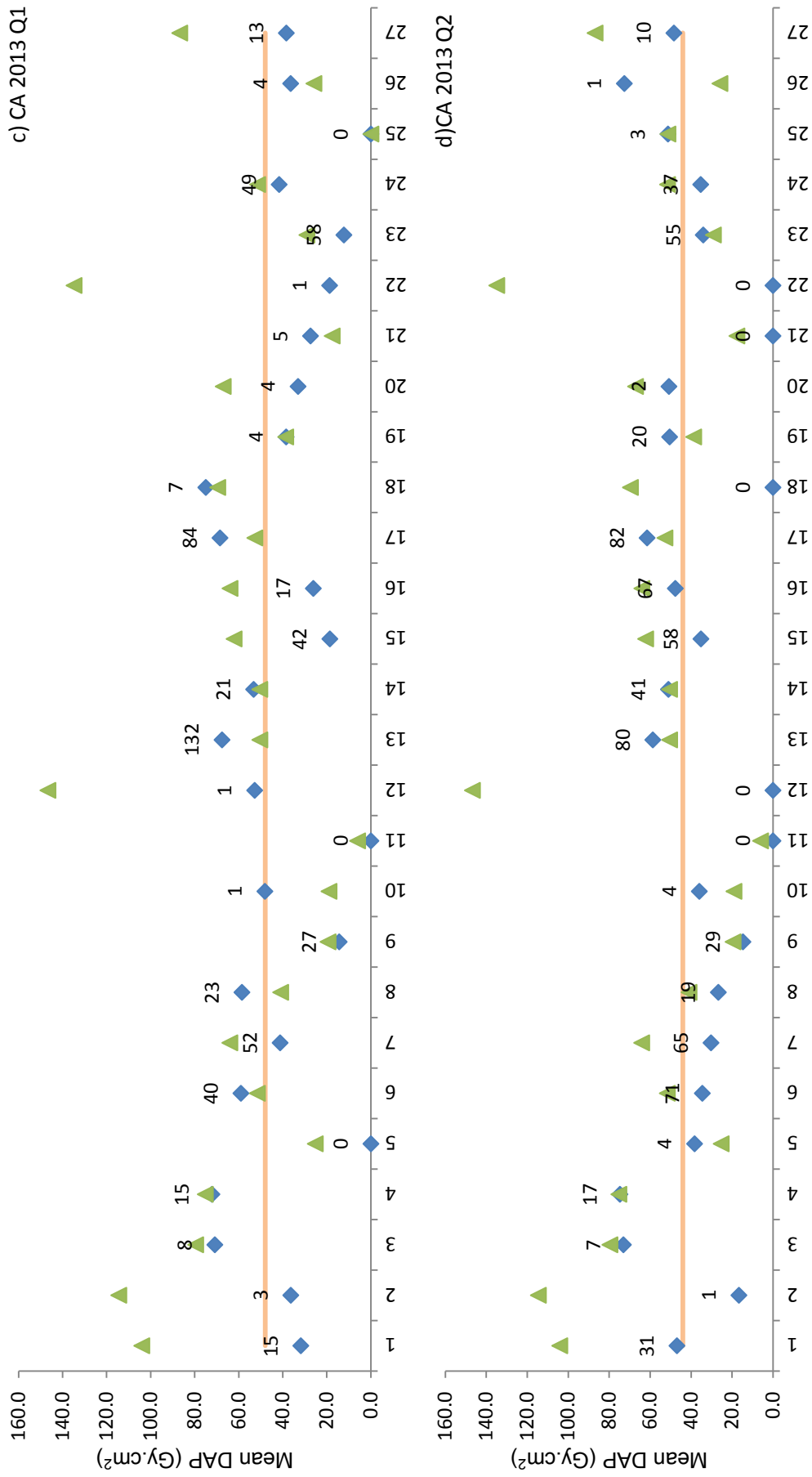


Figure 4.2.1.3 (c-d): Mean CA DAP readings displayed per theatre (x-axis) as recorded for (c) 2013 Q1 and (d) 2013 Q2. The triangles (▲) indicate baseline values recorded in 2012 Q3 and the diamonds (◆) indicate readings for the respective period. The data labels indicate, per theatre, the number of cases recorded. The horizontal line represents the mean DAP for all cases.

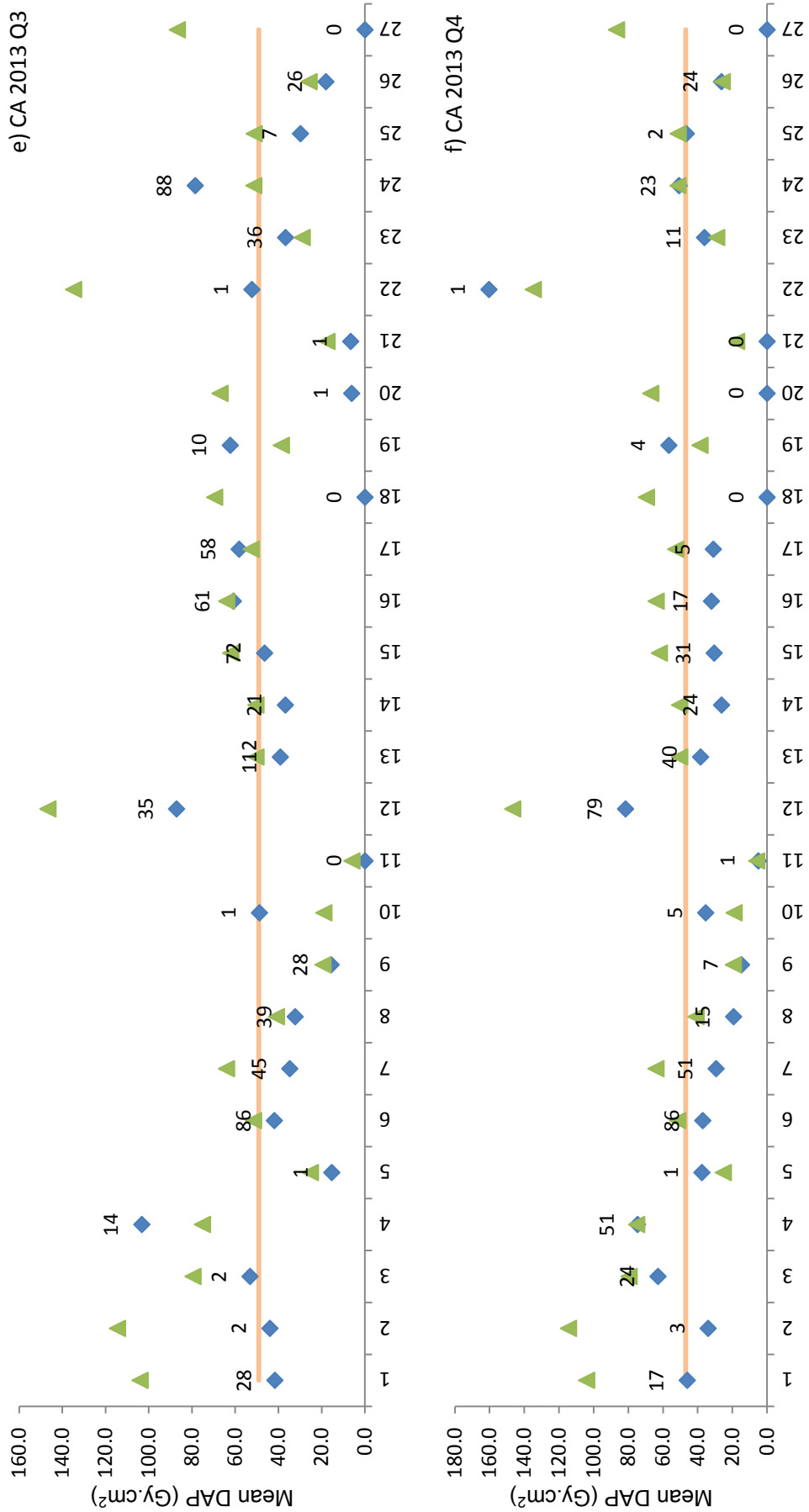


Figure 4.2.1.4 (e-f): Mean CA DAP readings displayed per theatre (x-axis) as recorded for (e) 2013 Q3 and (f) 2013 Q4. The triangles (▲) indicate baseline values recorded in 2012 Q3 and the diamonds (◆) indicate readings for the respective period. The data labels indicate, per theater, the number of cases recorded. The horizontal line represents the mean DAP for all cases.

## 4.2.2 Coronary Angiography & Left Ventriculography

Table 4.2.2.1: The DAP readings recorded for CA+LV displayed and analyzed for each quarter. The total number for procedures recorded for all six quarters was 7547. Indicated in bold is the baseline DRL calculated for quarter Q3 2012 as  $76.8 \text{ Gy.cm}^2$  and the DRL calculated in Q4 2013 is  $63.3 \text{ Gy.cm}^2$ . The amount of procedures is indicated as (*n*) and the standard deviation and inter-quartile ranges for each quarter are also shown.

CA + LV	2012 Q3	2012 Q4	2013 Q1	2013 Q2	2013 Q3	2013 Q4
<i>n</i>	1548	1207	1308	1461	1205	818
Average ( $\text{Gy.cm}^2$ )	64.5	57.9	48.7	51.4	57.5	50.9
1 <sup>st</sup> Quartile ( $\text{Gy.cm}^2$ )	25.4	23.1	21.8	22.9	24.8	25.3
3 <sup>rd</sup> Quartile ( $\text{Gy.cm}^2$ )	<b>76.8</b>	66.5	63.2	66.2	72.2	<b>63.3</b>
Inter-quartile range	51.3	43.3	41.4	43.3	47.4	38.0
Standard deviation	71.2	70.6	43.6	44.1	54.0	47.7

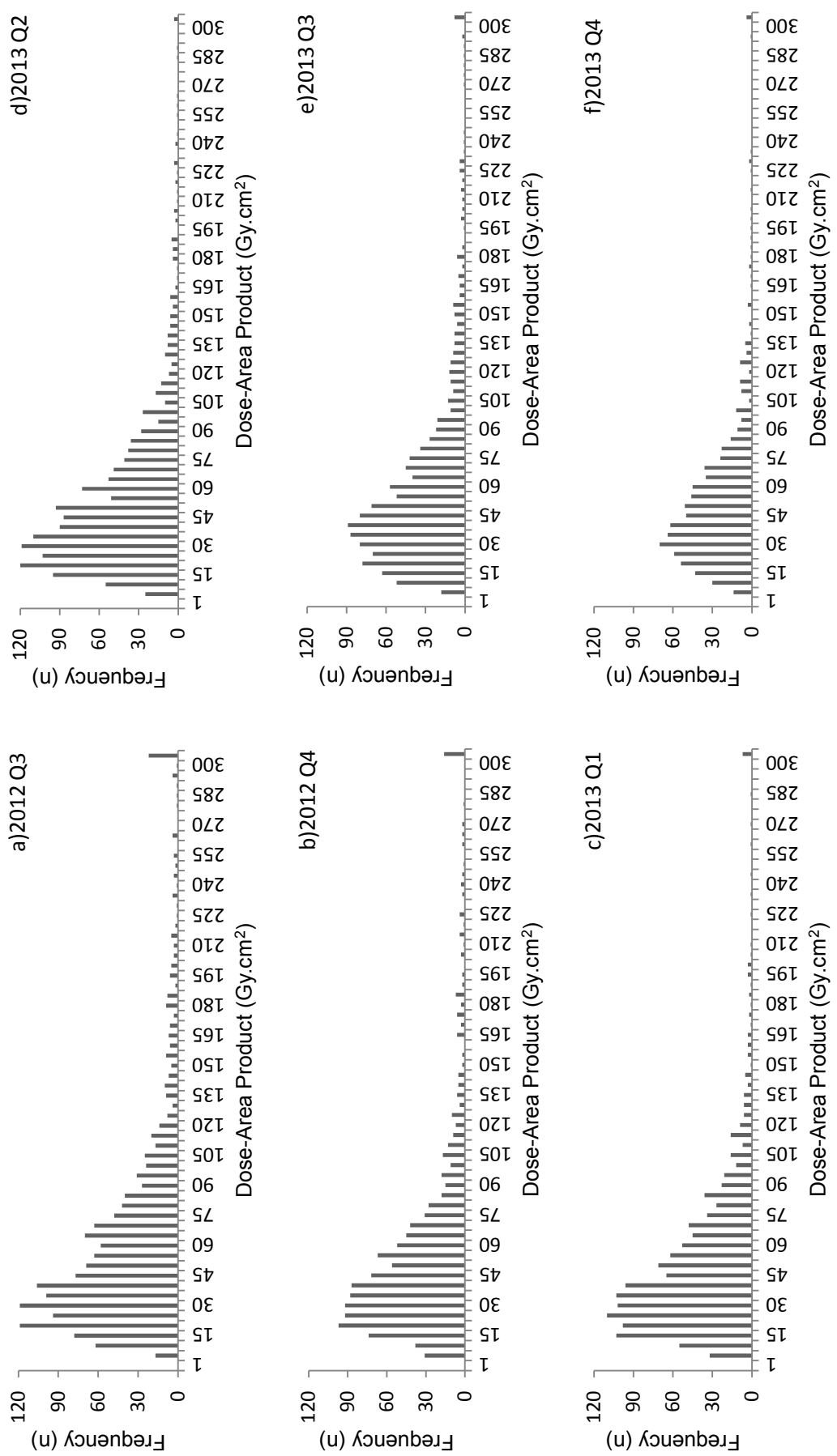


Figure 4.2.2.1 (a-f): Histograms of CA + LV DAP readings displayed for quarter (a) 2012 Q3, (b) 2012 Q4, (c) 2013 Q1, (d) 2013 Q2, (e) 2013 Q3 and (f) 2013 Q4. The frequency (n) shows the amount of procedures recorded at different DAP levels (Gy.cm<sup>2</sup>).

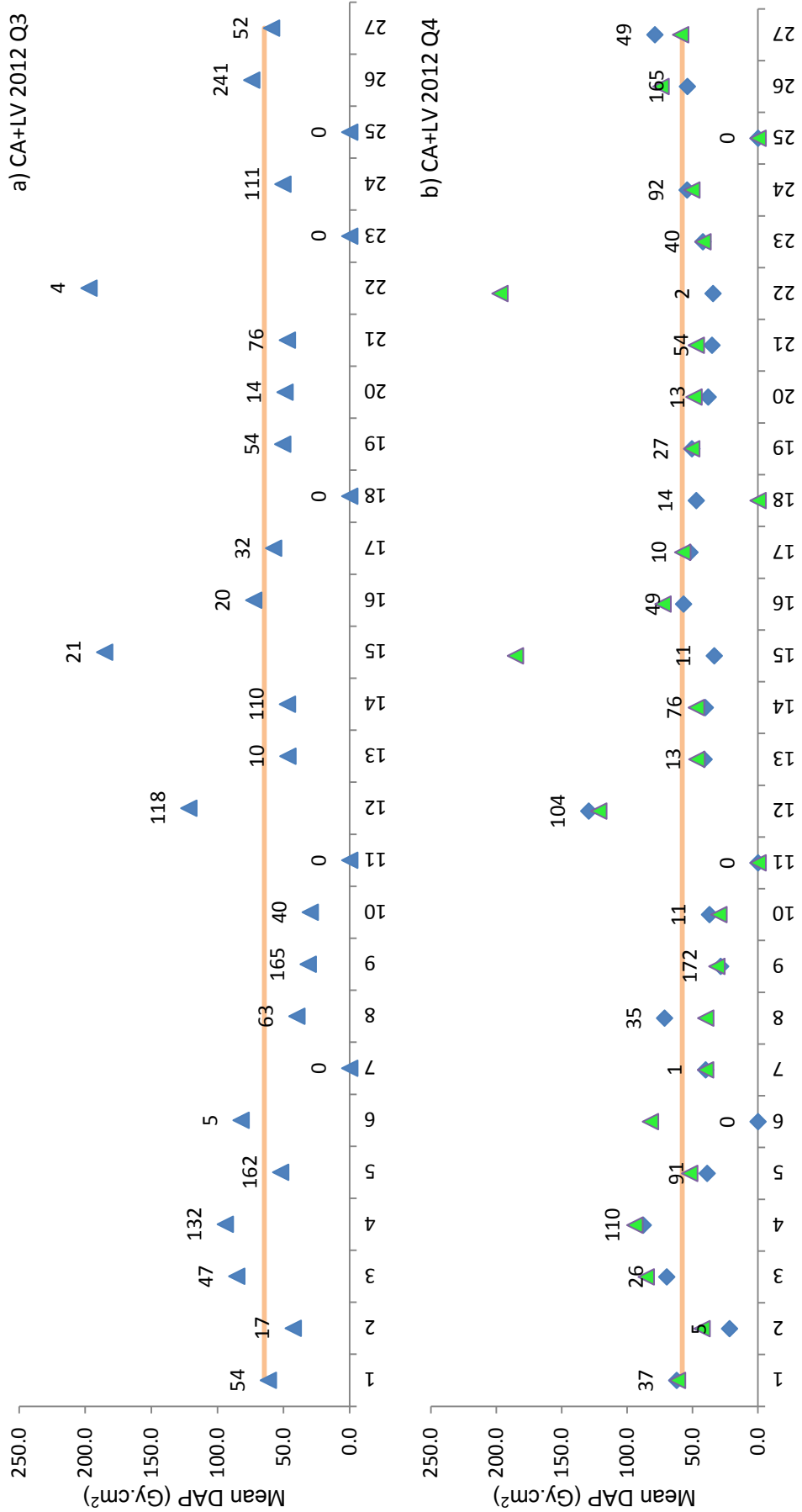


Figure 4.2.2.2 (a-b): Mean CA + LV DAP readings displayed per theatre (x-axis) as recorded for (a) 2012 Q3 and (b) 2012 Q4. The triangles (▲) indicate baseline values recorded in Q3 2012 and the diamonds (◆) indicate readings for the respective period. The data labels indicate, per theatre, the number of cases recorded. The horizontal line represents the mean DAP for all cases.

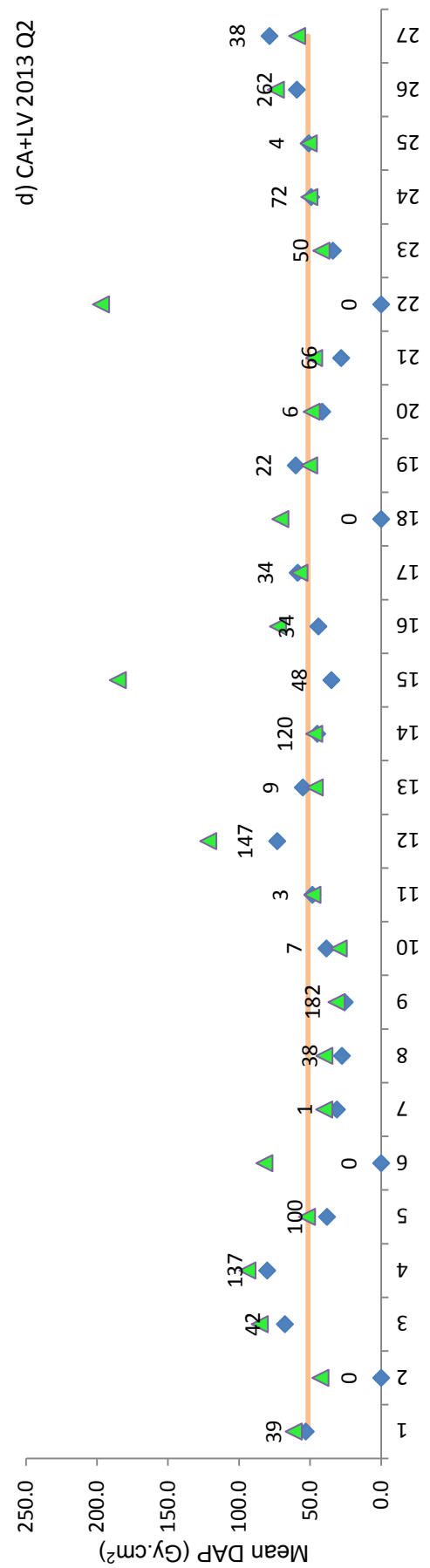
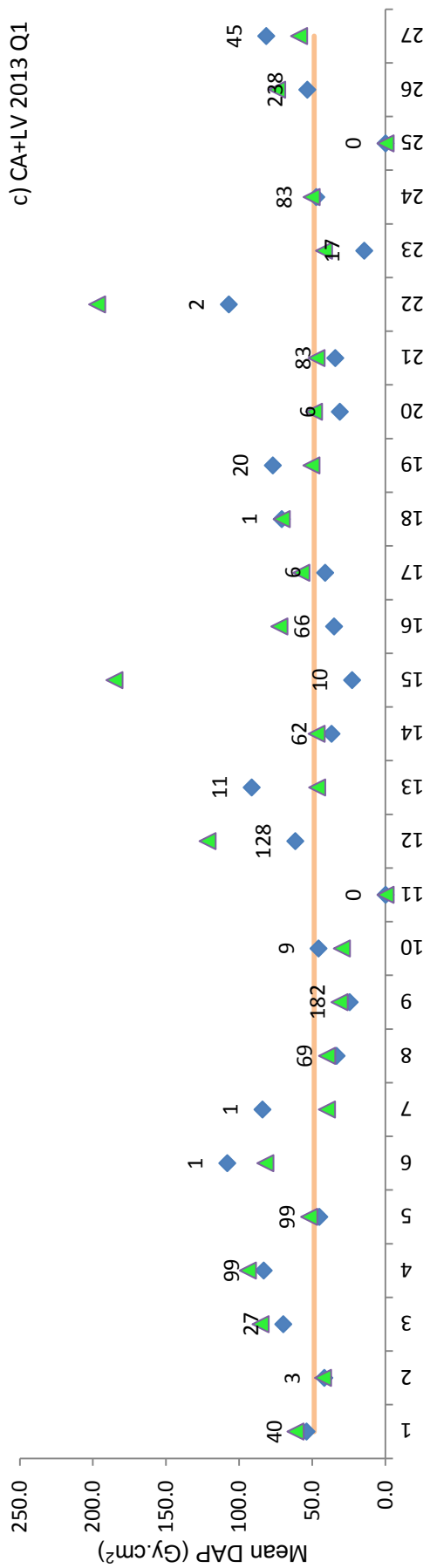


Figure 4.2.2.3 (c-d): Mean CA + LV DAP readings displayed per theatre (x-axis) as recorded for (c) 2013 Q1 and (d) 2013 Q2. The triangles (▲) indicate baseline values recorded in 2012 Q3 and the diamonds (◆) indicate readings for the respective period. The data labels indicate, per theatre, the number of cases recorded. The horizontal line represents the mean DAP for all cases.

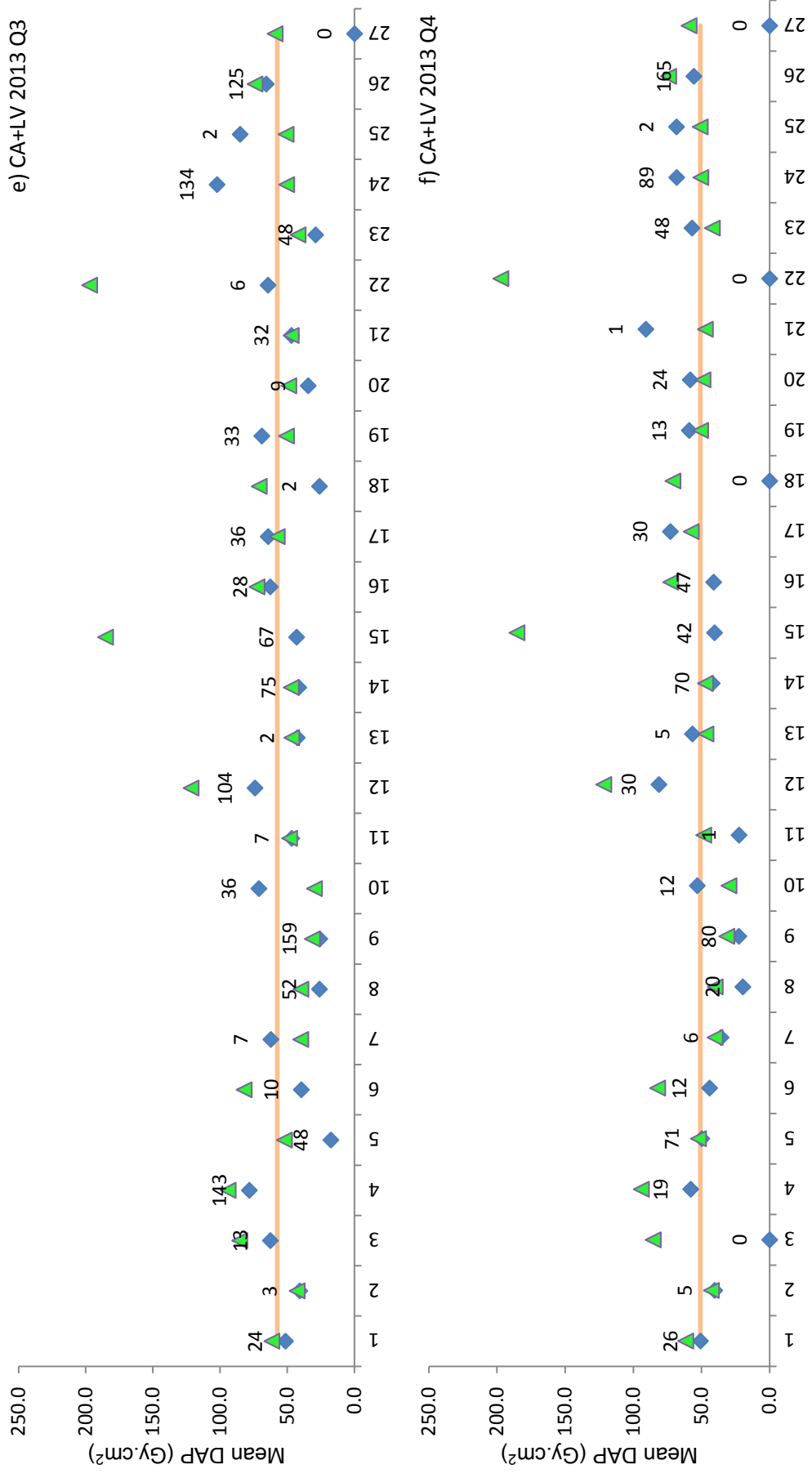


Figure 4.2.2.4 (e-f): Mean CA + LV DAP readings displayed per theatre (x-axis) as recorded for (e) 2013 Q3 and (f) 2013 Q4. The triangles (▲) indicate baseline values recorded in 2012 Q3 and the diamonds (◆) indicate readings for the respective period. The data labels indicate, per theatre, the number of cases recorded. The horizontal line represents the mean DAP for all cases.

### 4.2.3 Coronary Angiography & PTCA + 1 Stent

Table 4.2.3.1: The DAP readings recorded for CA + PTCA + 1 Stent displayed and analyzed for each quarter. The total number for procedures recorded for all six quarters was 1885. Indicated in bold is the baseline DRL calculated for quarter Q3 2012 as 192.1 Gy.cm<sup>2</sup> and the DRL calculated in Q4 2013 is 175.7 Gy.cm<sup>2</sup>. The amount of procedures is indicated as (*n*) and the standard deviation and inter-quartile ranges for each quarter are also shown.

CA + PTCA + 1 Stent	2012 Q3	2012 Q4	2013 Q1	2013 Q2	2013 Q3	2013 Q4
<i>n</i>	496	264	267	359	314	185
Average (Gy.cm <sup>2</sup> )	147.2	118.0	129.6	130.5	129.1	137.0
1 <sup>st</sup> Quartile (Gy.cm <sup>2</sup> )	65.7	54.8	58.8	62.6	54.0	66.2
3 <sup>rd</sup> Quartile (Gy.cm <sup>2</sup> )	<b>192.1</b>	157.2	166.9	163.9	179.0	<b>175.7</b>
Inter-quartile range	126.4	102.5	108.1	101.3	125.0	109.5
Standard deviation	115.8	99.1	105.5	110.3	97.9	104.2

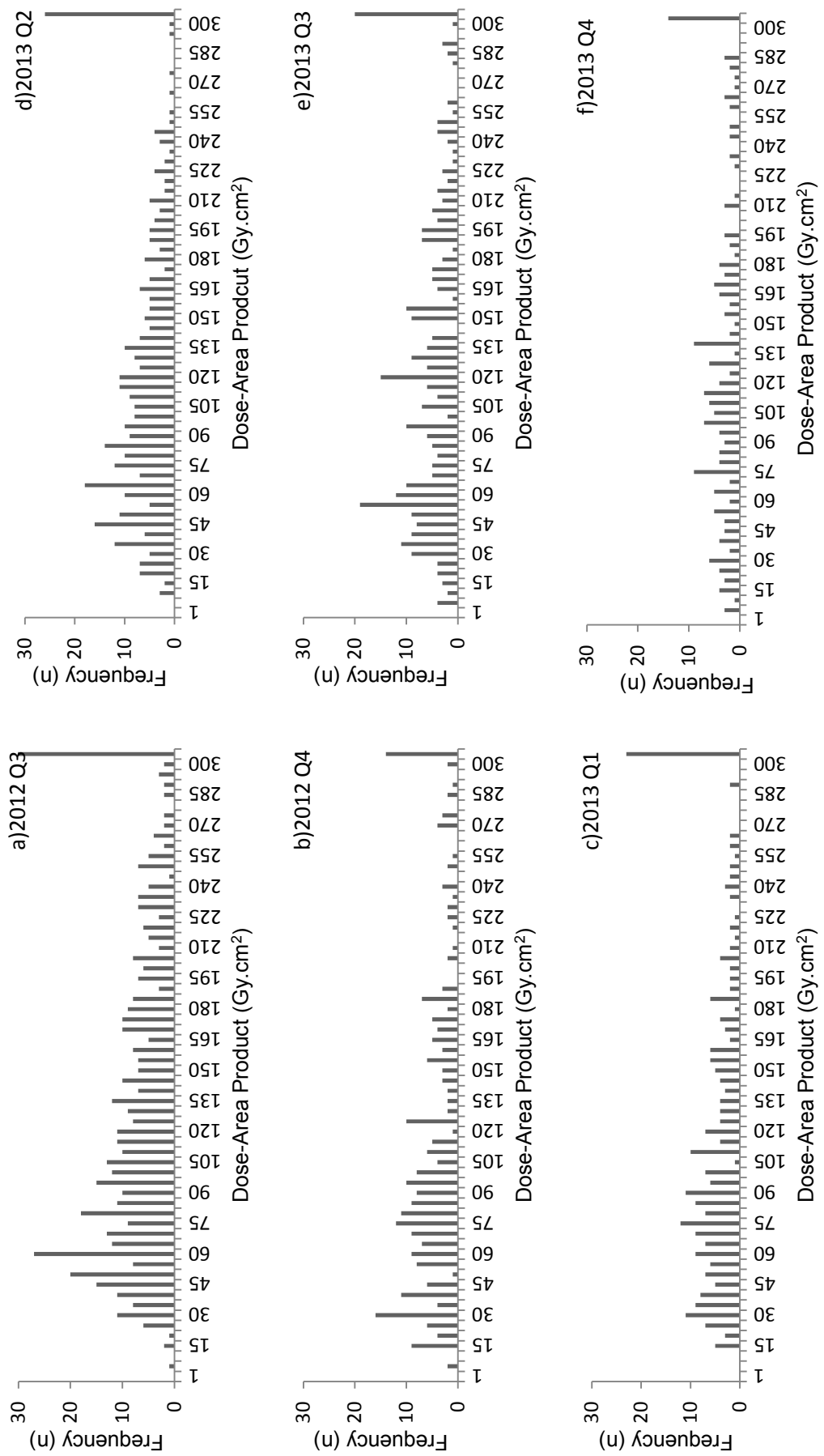


Figure 4.2.3.1 (a-f): Histograms of CA + PTCA + 1 Stent DAP readings displayed for quarter (a) 2012 Q3, (b) 2012 Q4, (c) 2013 Q1, (d) 2013 Q2, (e) 2013 Q3 and (f) 2013 Q4. The frequency (n) shows the amount of procedures recorded at different DAP levels (Gy.cm<sup>2</sup>).

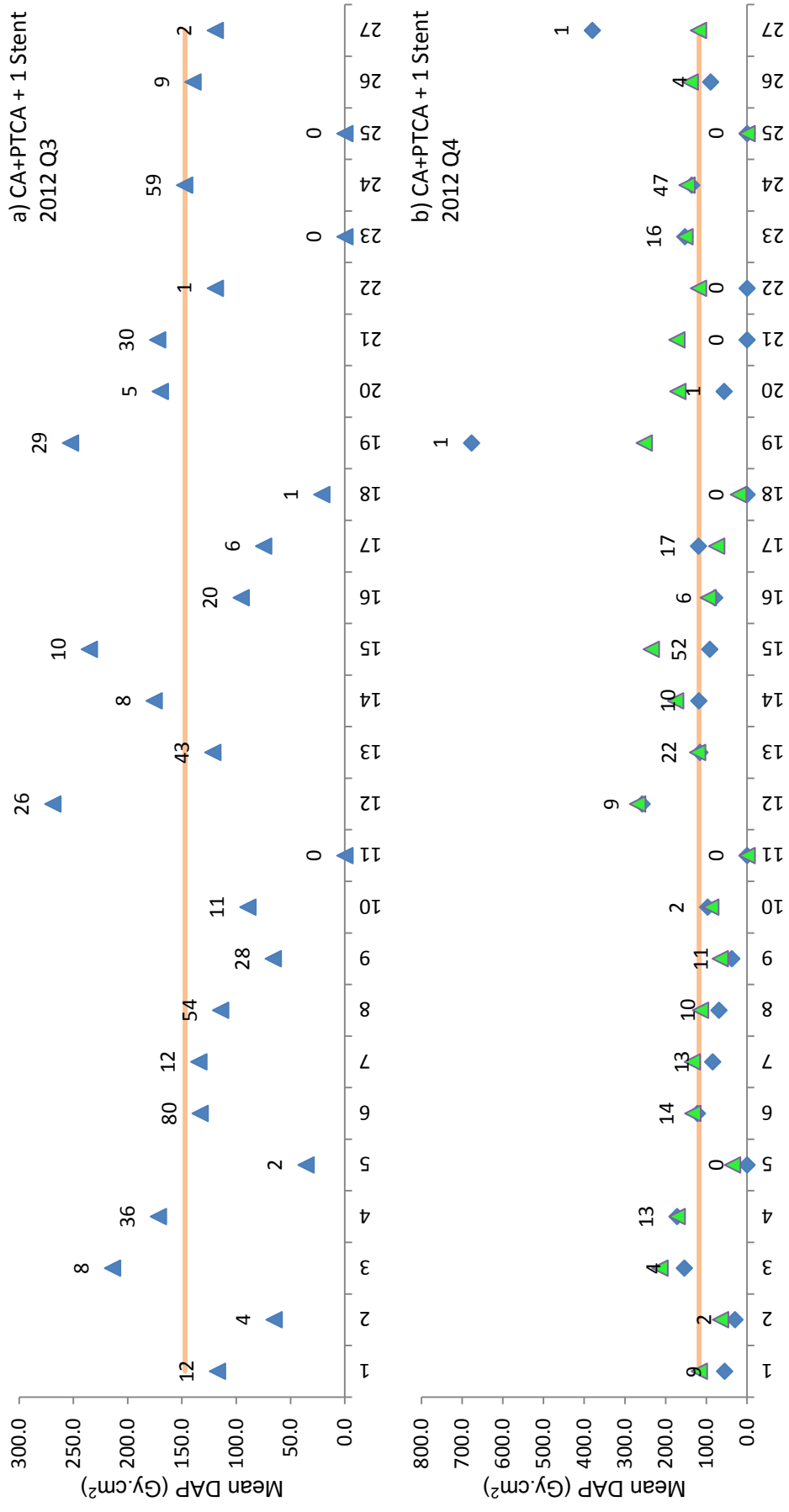


Figure 4.2.3.2 (a-b): Mean CA + PTCA + 1 Stent DAP readings displayed per theatre (x-axis) as recorded for (a) 2012 Q3 and (b) 2012 Q4. The triangles (▲) indicate baseline values recorded in Q3 2012 and the diamonds (◆) indicate readings for the respective period. The data labels indicate, per theatre, the number of cases recorded. The horizontal line represents the mean DAP for all cases.

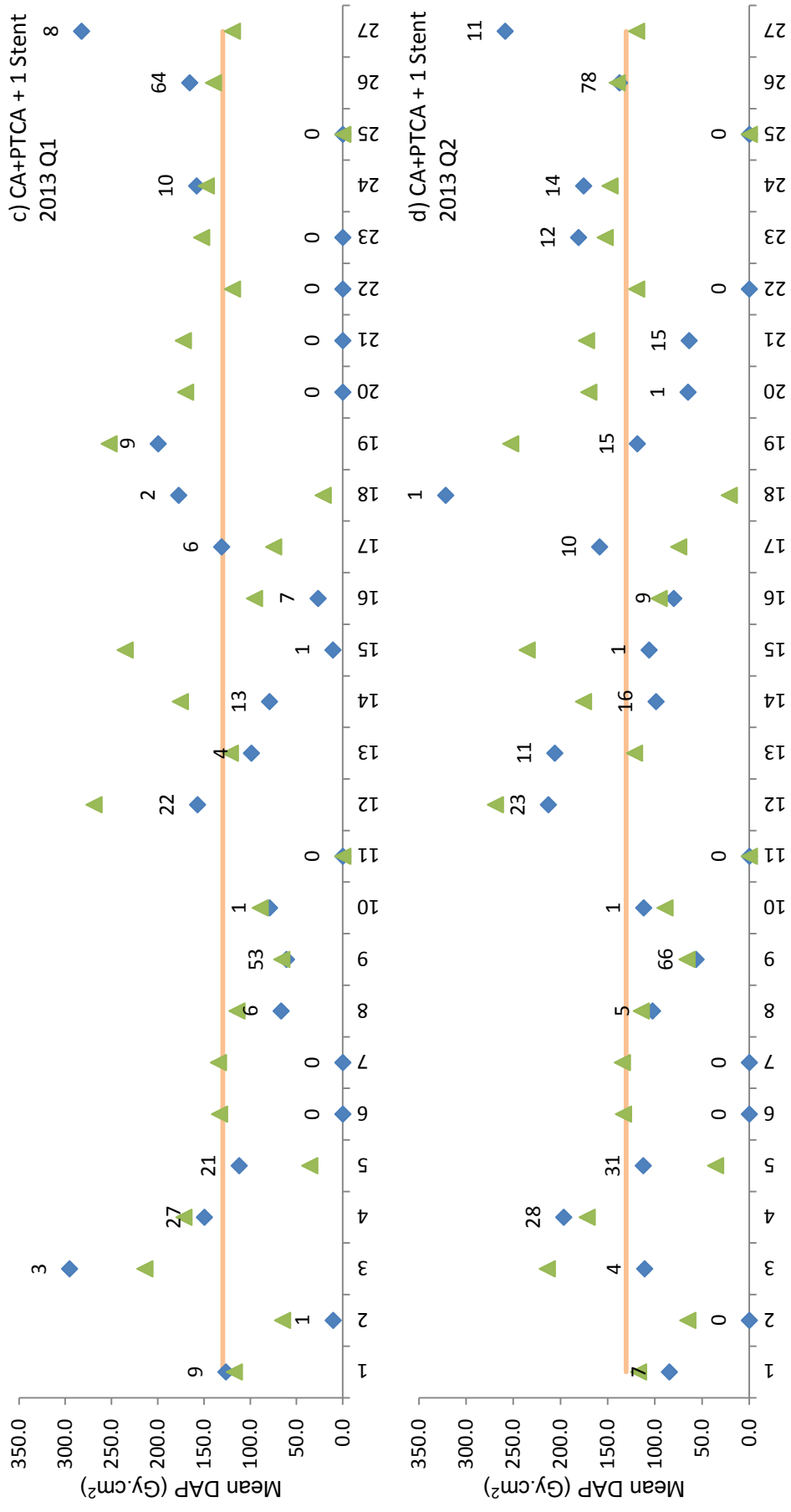


Figure 4.2.3.3 (c-d): Mean CA + PTCA + 1 Stent DAP readings displayed per theatre (x-axis) as recorded for (c) 2013 Q1 and (d) 2013 Q2. The triangles (▲) indicate baseline values recorded in 2012 Q3 and the diamonds (◆) indicate readings for the respective period. The data labels indicate, per theater, the number of cases recorded. The horizontal line represents the mean DAP for all cases.

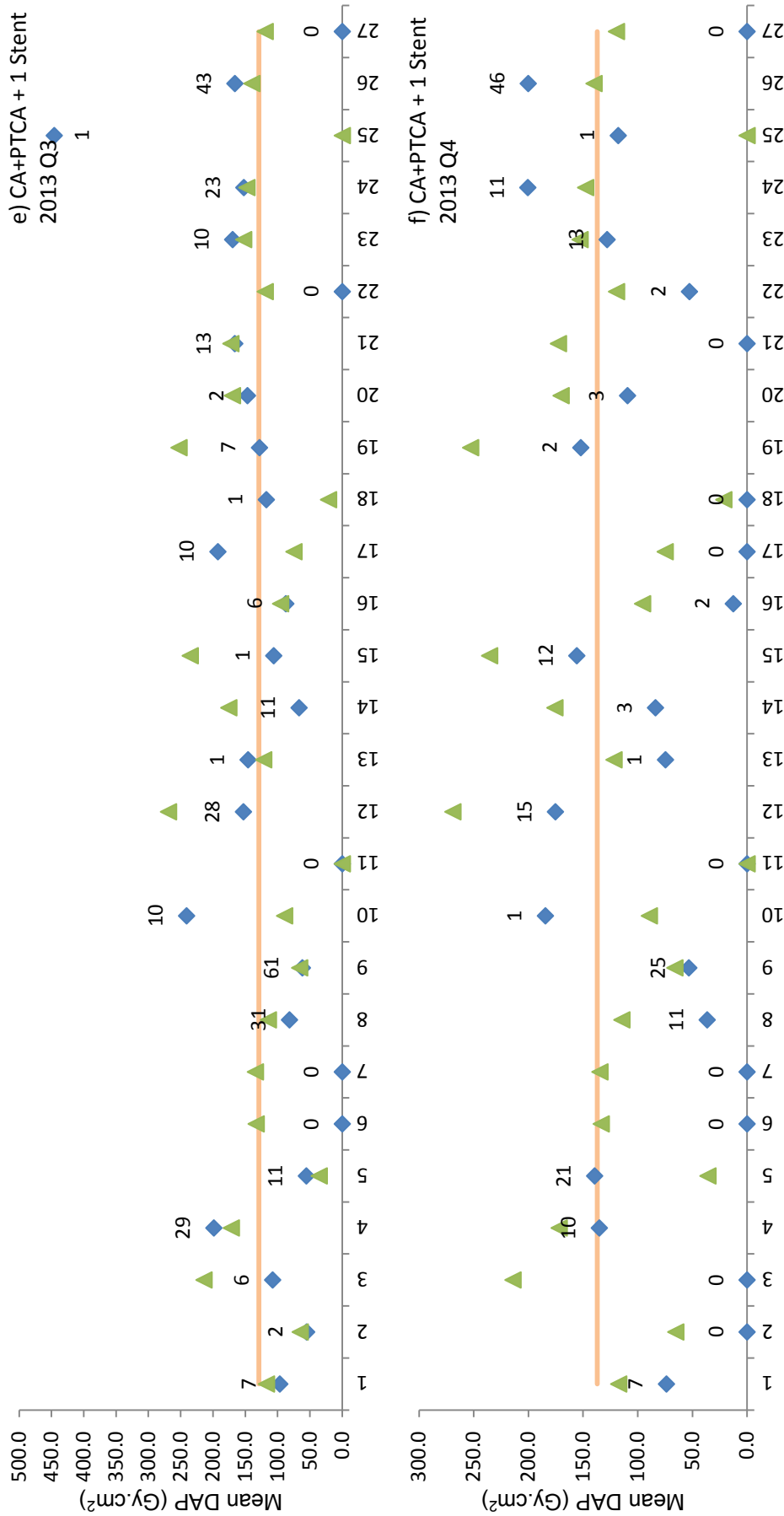


Figure 4.2.3.4 (e-f): Mean CA + PTCA + 1 Stent DAP readings displayed per theatre (x-axis) as recorded for (e) 2013 Q3 and (f) 2013 Q4. The triangles (▲) indicate baseline values recorded in 2012 Q3 and the diamonds (◆) indicate readings for the respective period. The data labels indicate, per theater, the number of cases recorded. The horizontal line represents the mean DAP for all cases.

#### 4.2.4 Permanent Pacemaker

Table 4.2.4.1: The DAP readings recorded for PPM displayed and analyzed for each quarter. The total number for procedures recorded for all six quarters was 1175. Indicated in bold is the baseline DRL calculated for quarter Q3 2012 as 40.9 Gy.cm<sup>2</sup> and the DRL calculated in Q4 2013 is 35.5 Gy.cm<sup>2</sup>. The amount of procedures is indicated as (*n*) and the standard deviation and inter-quartile ranges for each quarter are also shown.

PPM	2012 Q3	2012 Q4	2013 Q1	2013 Q2	2013 Q3	2013 Q4
<i>n</i>	284	182	214	204	175	116
Average (Gy.cm <sup>2</sup> )	37.0	47.5	33.3	33.4	35.6	28.6
1 <sup>st</sup> Quartile (Gy.cm <sup>2</sup> )	8.5	6.6	8.0	6.1	4.8	5.0
3 <sup>rd</sup> Quartile (Gy.cm <sup>2</sup> )	<b>40.9</b>	46.0	43.0	42.4	42.5	<b>35.5</b>
Inter-quartile range	32.4	39.5	35.0	36.3	37.8	30.5
Standard deviation	56.8	98.8	43.4	40.5	53.5	34.3

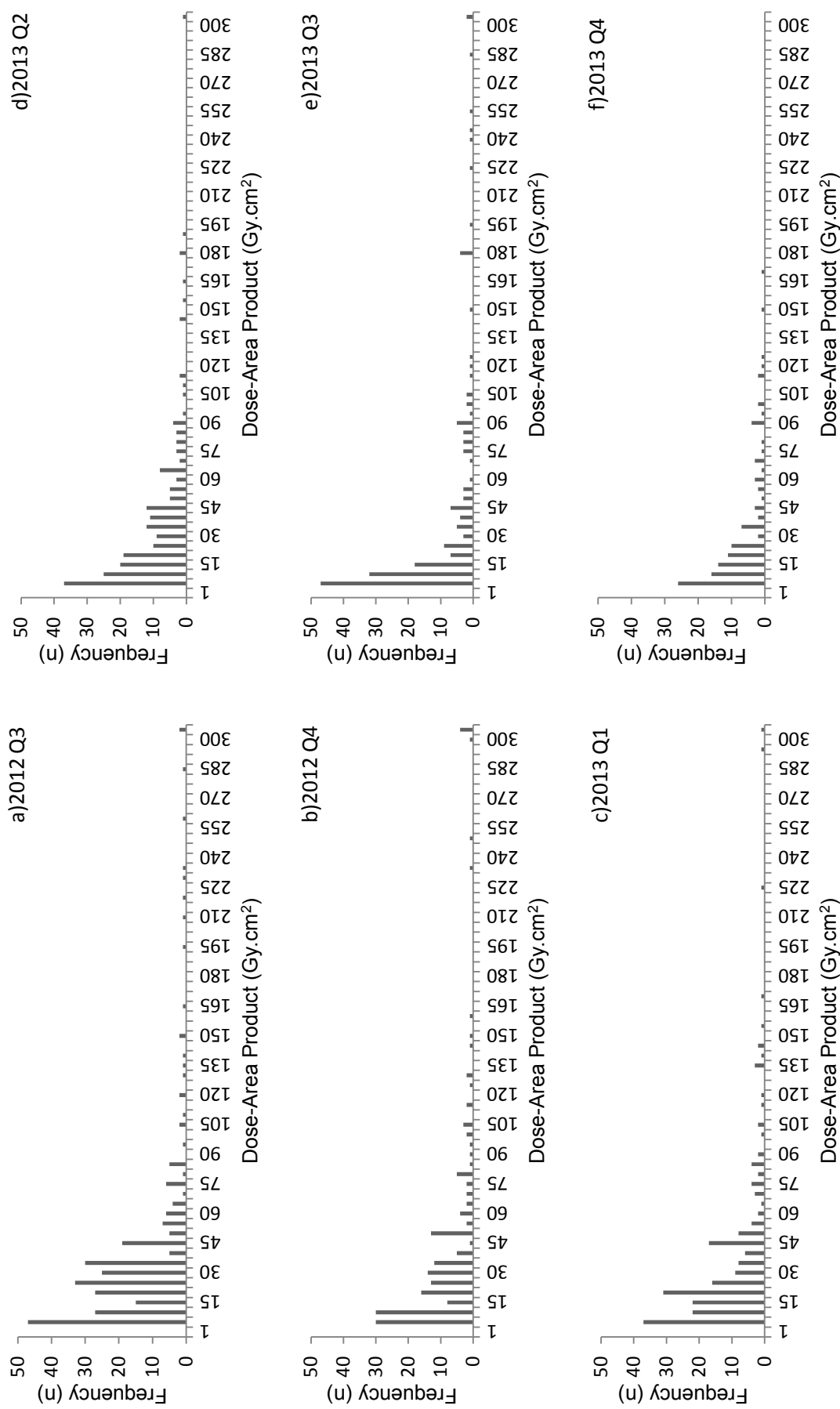
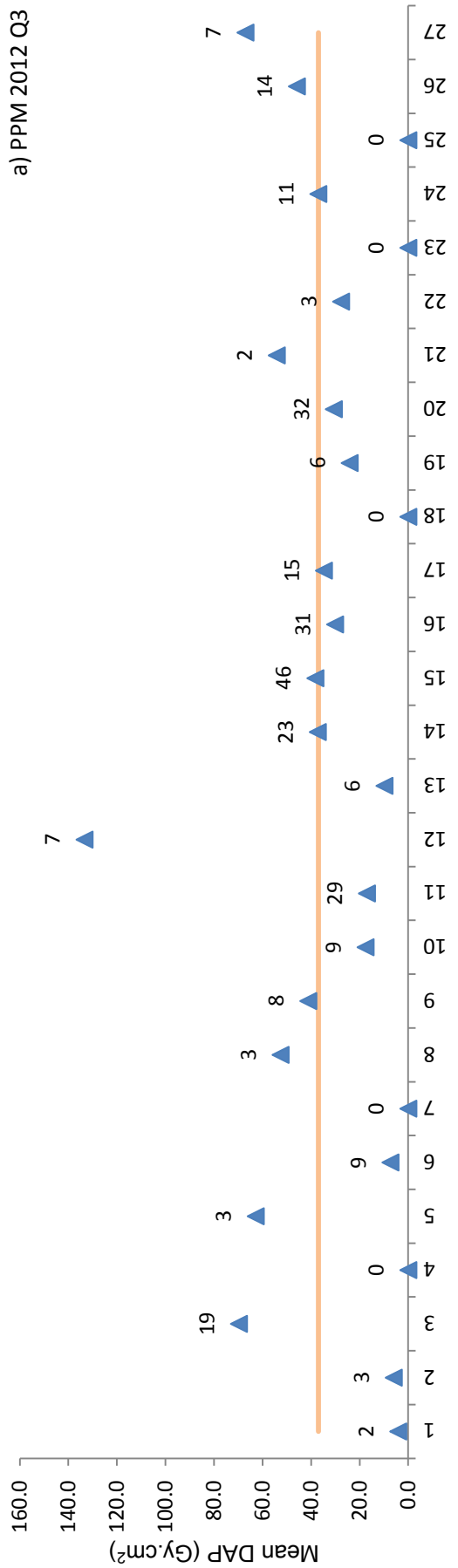


Figure 4.2.4.1 (a-f): Histograms of PPM DAP readings displayed for quarter (a) 2012 Q3, (b) 2012 Q4, (c) 2013 Q1, (d) 2013 Q2, (e) 2013 Q3 and (f) 2013 Q4. The frequency (n) shows the amount of procedures recorded at different DAP levels (Gy.cm<sup>2</sup>).

a) PPM 2012 Q3



b) PPM 2012 Q4

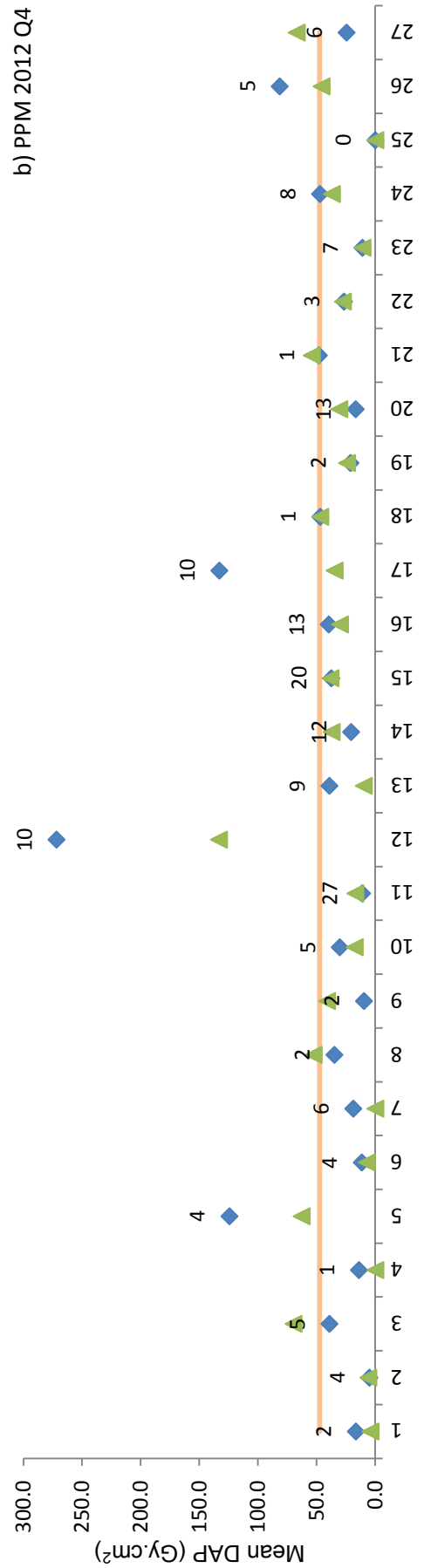


Figure 4.2.4.2 (a-b): Mean PPM DAP readings displayed per theatre (x-axis) as recorded for (a) 2012 Q3 and (b) 2012 Q4. The triangles (▲) indicate baseline values recorded in Q3 2012 and the diamonds (◆) indicate readings for the respective period. The data labels indicate, per theatre, the number of cases recorded. The horizontal line represents the mean DAP for all cases.

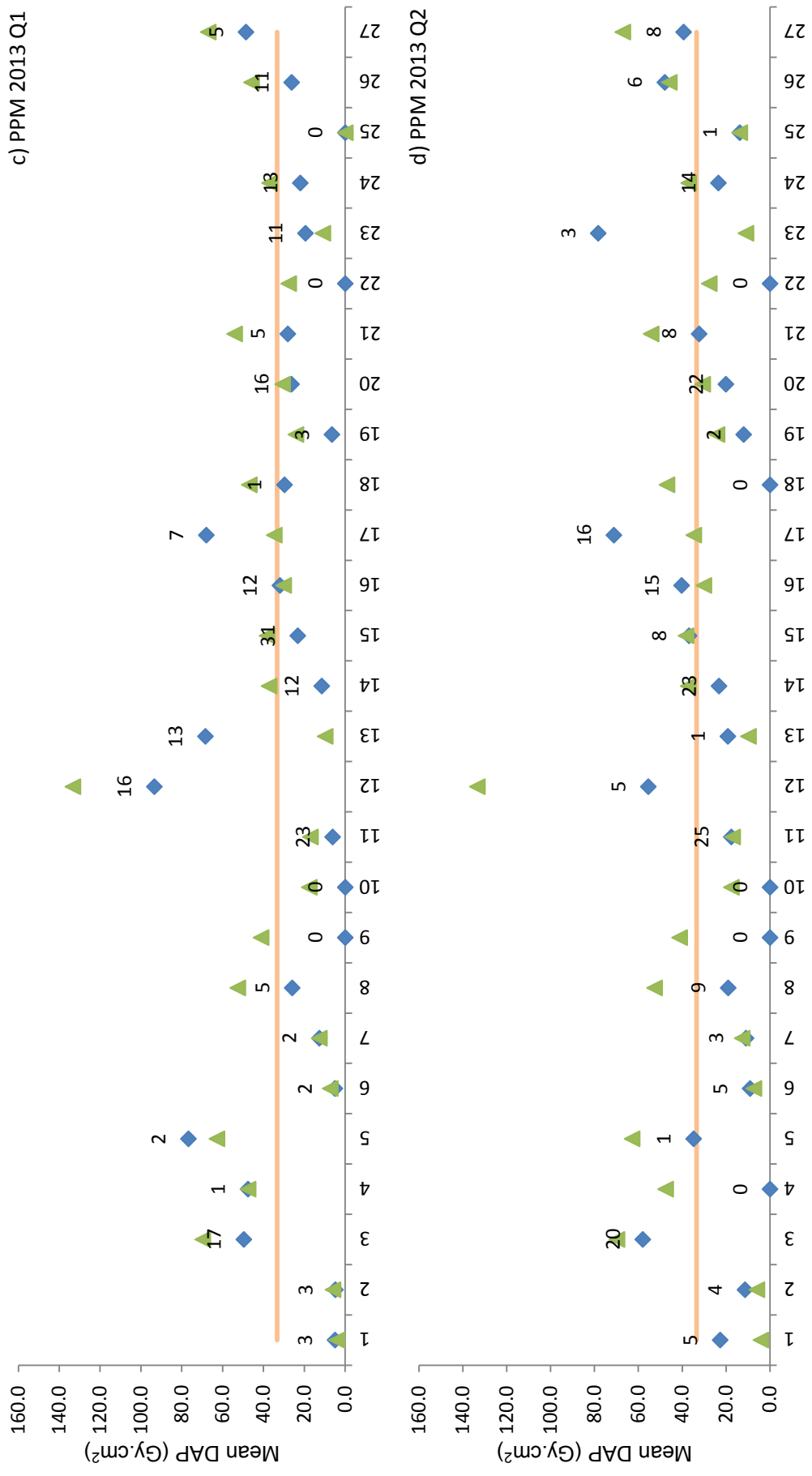


Figure 4.2.4.3 (c-d): Mean PPM DAP readings displayed per theatre (x-axis) as recorded for (c) 2013 Q1 and (d) 2013 Q2. The triangles (▲) indicate baseline values recorded in 2012 Q3 and the diamonds (◆) indicate readings for the respective period. The data labels indicate, per theatre, the number of cases recorded. The horizontal line represents the mean DAP for all cases.

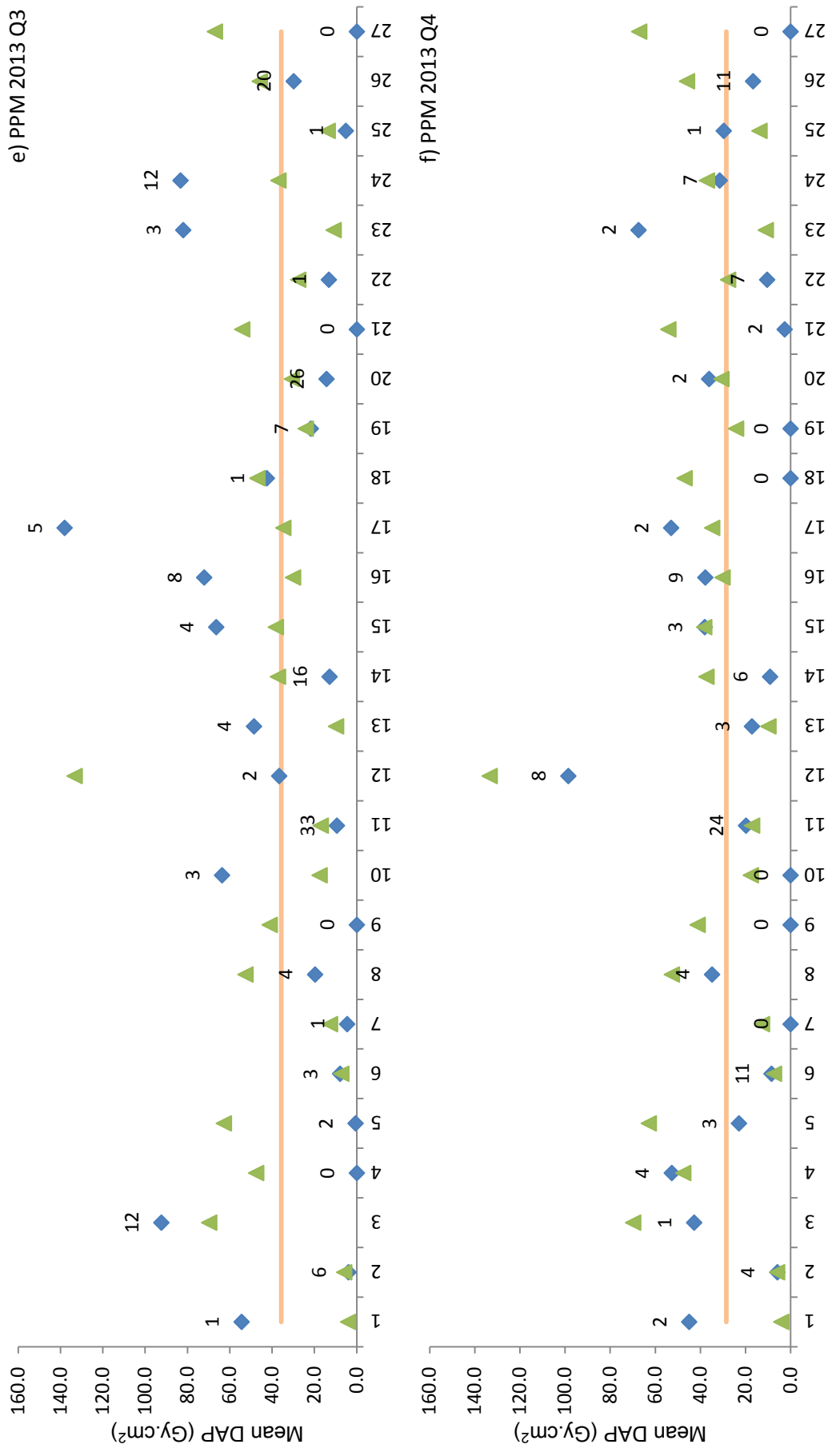


Figure 4.2.4.4 (e-f): Mean PPM DAP readings displayed per theatre (x-axis) as recorded for (e) 2013 Q3 and (f) 2013 Q4. The triangles (▲) indicate baseline values recorded in 2012 Q3 and the diamonds (◆) indicate readings for the respective period. The data labels indicate, per theatre, the number of cases recorded. The horizontal line represents the mean DAP for all cases.

#### 4.2.5 Bi-Ventricular Permanent Pacemaker

Table 4.2.5.1: The DAP readings recorded for Bi-Ventricular Pacemakers are displayed and analyzed for each quarter. The total number for procedures recorded for all six quarters was 280. Indicated in bold is the baseline DRL calculated for quarter Q3 2012 as  $144.4 \text{ Gy.cm}^2$  and the DRL calculated in Q4 2013 is  $116.5 \text{ Gy.cm}^2$ . The amount of procedures is indicated as (*n*) and the standard deviation and inter-quartile ranges for each quarter are also shown.

Bi-Vent PPM	2012 Q3	2012 Q4	2013 Q1	2013 Q2	2013 Q3	2013 Q4
<i>n</i>	84	53	43	44	30	26
Average (Gy.cm <sup>2</sup> )	134.8	94.8	107.6	160.2	155.9	106.9
1 <sup>st</sup> Quartile (Gy.cm <sup>2</sup> )	34.0	24.4	23.8	35.2	30.5	24.2
3 <sup>rd</sup> Quartile (Gy.cm <sup>2</sup> )	<b>144.4</b>	81.5	150.3	225.7	188.5	<b>116.5</b>
Inter-quartile range	110.3	57.1	126.5	190.6	158.0	92.3
Standard deviation	163.5	140.6	123.6	164.8	210.6	125.3

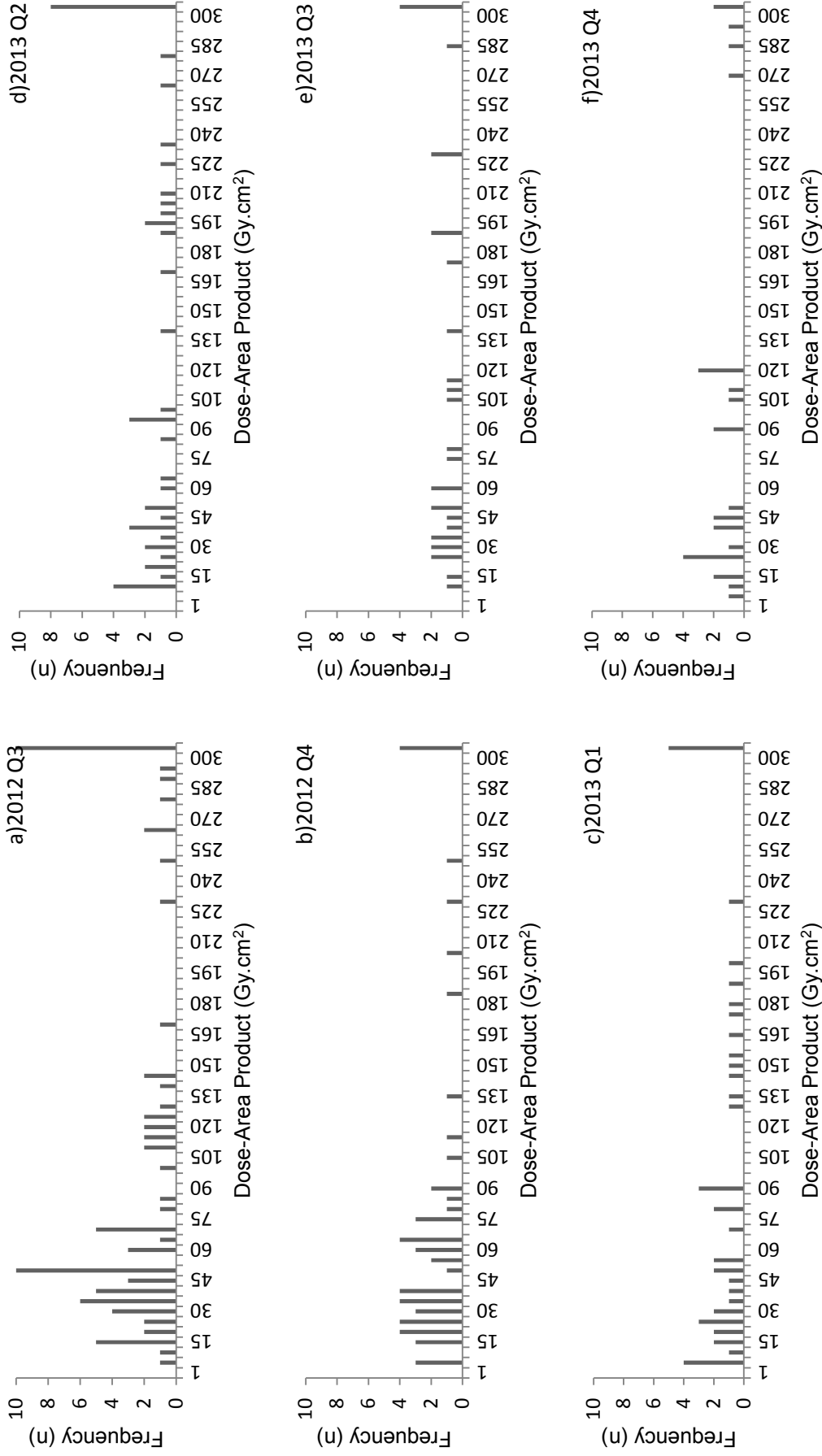


Figure 4.2.5.1 (a-f): Histograms of Bi-vent PPM DAP readings displayed for quarter (a) 2012 Q3, (b) 2012 Q4, (c) 2013 Q1, (d) 2013 Q2, (e) 2013 Q3 and (f) 2013 Q4. The frequency (n) shows the amount of procedures recorded at different DAP levels (Gy.cm<sup>2</sup>).

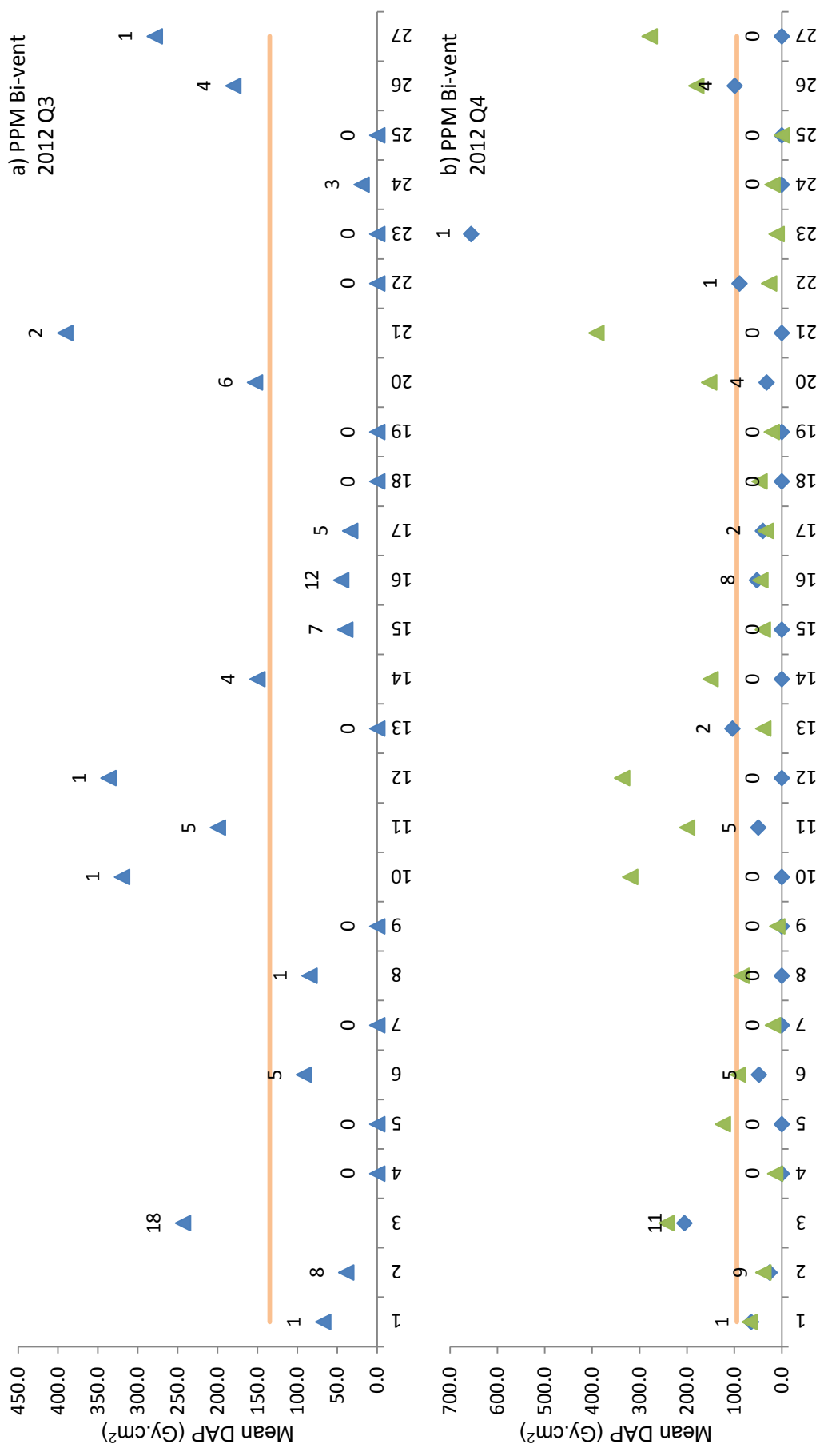


Figure 4.2.5.2 (a-b): Mean Bi-vent PPM DAP readings displayed per theatre (x-axis) as recorded for (a) 2012 Q3 and (b) 2012 Q4.

The triangles (▲) indicate baseline values recorded in Q3 2012 and the diamonds (◆) indicate readings for the respective period.

The data labels indicate, per theater, the number of cases recorded. The horizontal line represents the mean DAP for all cases.

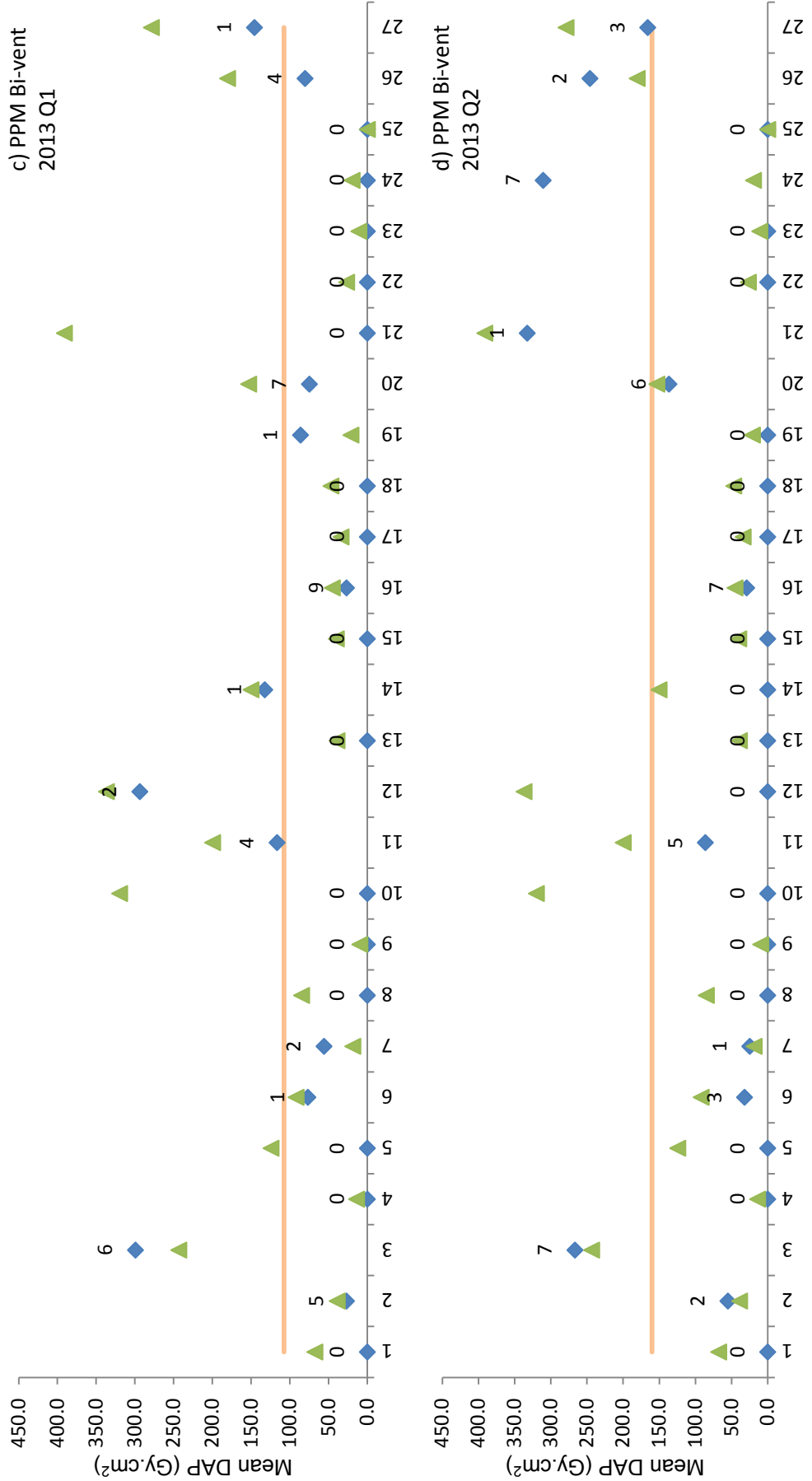


Figure 4.2.5.3 (c-d): Mean Bi-vent PPM DAP readings displayed per theatre (x-axis) as recorded for (c) 2013 Q1 and (d) 2013 Q2.

The triangles (▲) indicate baseline values recorded in 2012 Q3 and the diamonds (◆) indicate readings for the respective period.

The data labels indicate, per theatre, the number of cases recorded. The horizontal line represents the mean DAP for all cases.

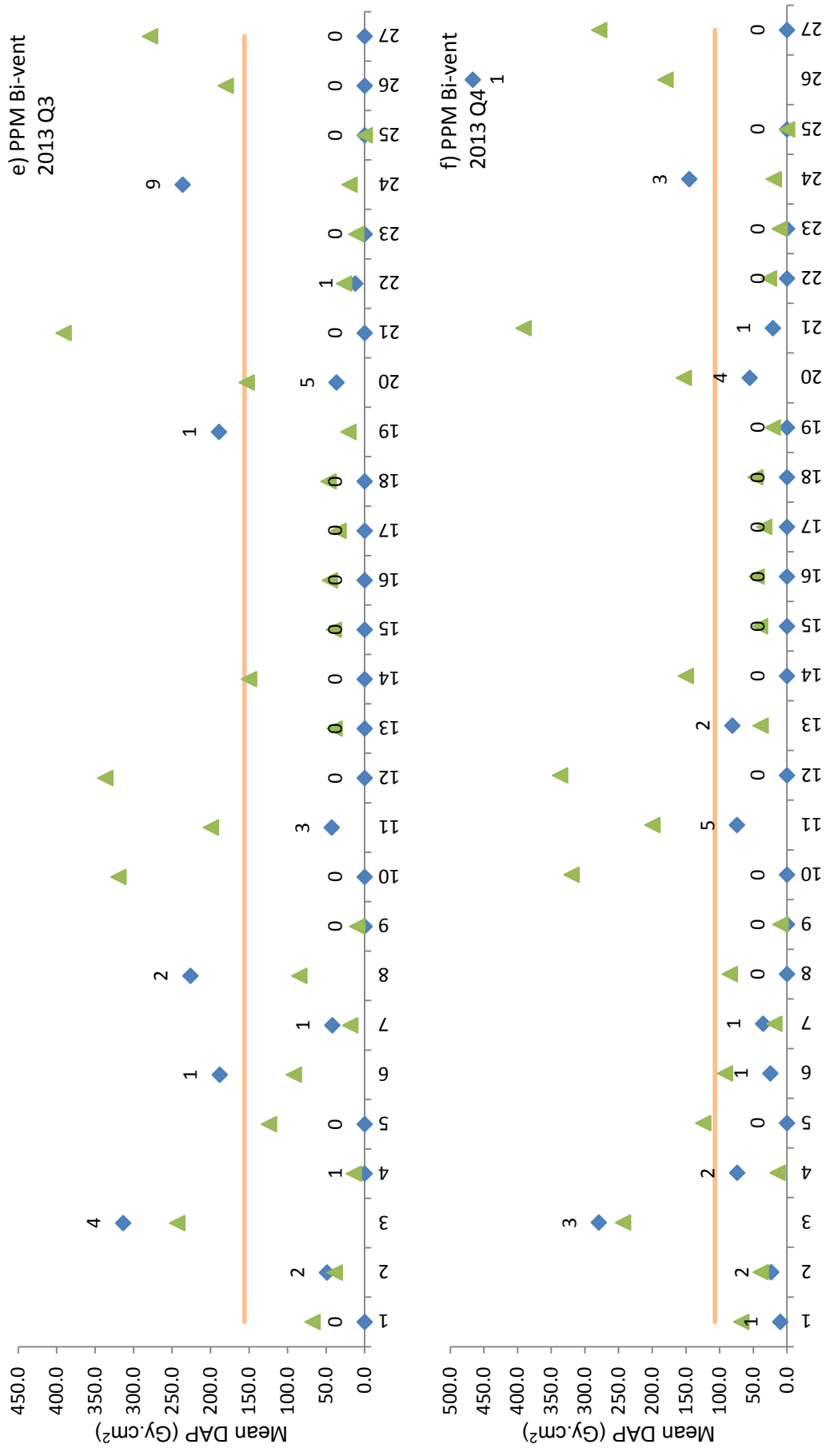


Figure 4.2.5.4 (e-f): Mean Bi-vent PPM DAP readings per theatre (x-axis) as recorded for (e) 2013 Q3 and (f) 2013 Q4.

The triangles (▲) indicate baseline values recorded in 2012 Q3 and the diamonds (◆) indicate readings for the respective period.

The data labels indicate, per theater, the number of cases recorded. The horizontal line represents the mean DAP for all cases.

## 4.2.6 Radiofrequency Ablation

Table 4.2.6.1: The DAP readings recorded for Radiofrequency Ablation displayed and analyzed for each quarter. The total number for procedures recorded for all six quarters was 675. Indicated in bold is the baseline DRL calculated for quarter Q3 2012 as 104.4 Gy.cm<sup>2</sup> and the DRL calculated in Q4 2013 is 65.7 Gy.cm<sup>2</sup>. The amount of procedures is indicated as (*n*) and the standard deviation and inter-quartile ranges for each quarter are also shown.

Ablation	2012 Q3	2012 Q4	2013 Q1	2013 Q2	2013 Q3	2013 Q4
<i>n</i>	183	98	93	115	130	56
Average (Gy.cm <sup>2</sup> )	84.8	78.6	59.4	56.0	53.6	48.4
1 <sup>st</sup> Quartile (Gy.cm <sup>2</sup> )	16.3	10.2	12.4	10.3	8.5	8.5
3 <sup>rd</sup> Quartile (Gy.cm <sup>2</sup> )	<b>104.4</b>	92.2	86.1	75.4	66.7	<b>65.7</b>
Inter-quartile range	88.0	81.9	73.7	65.1	58.3	57.2
Standard deviation	108.8	116.8	70.8	77.8	68.4	53.2

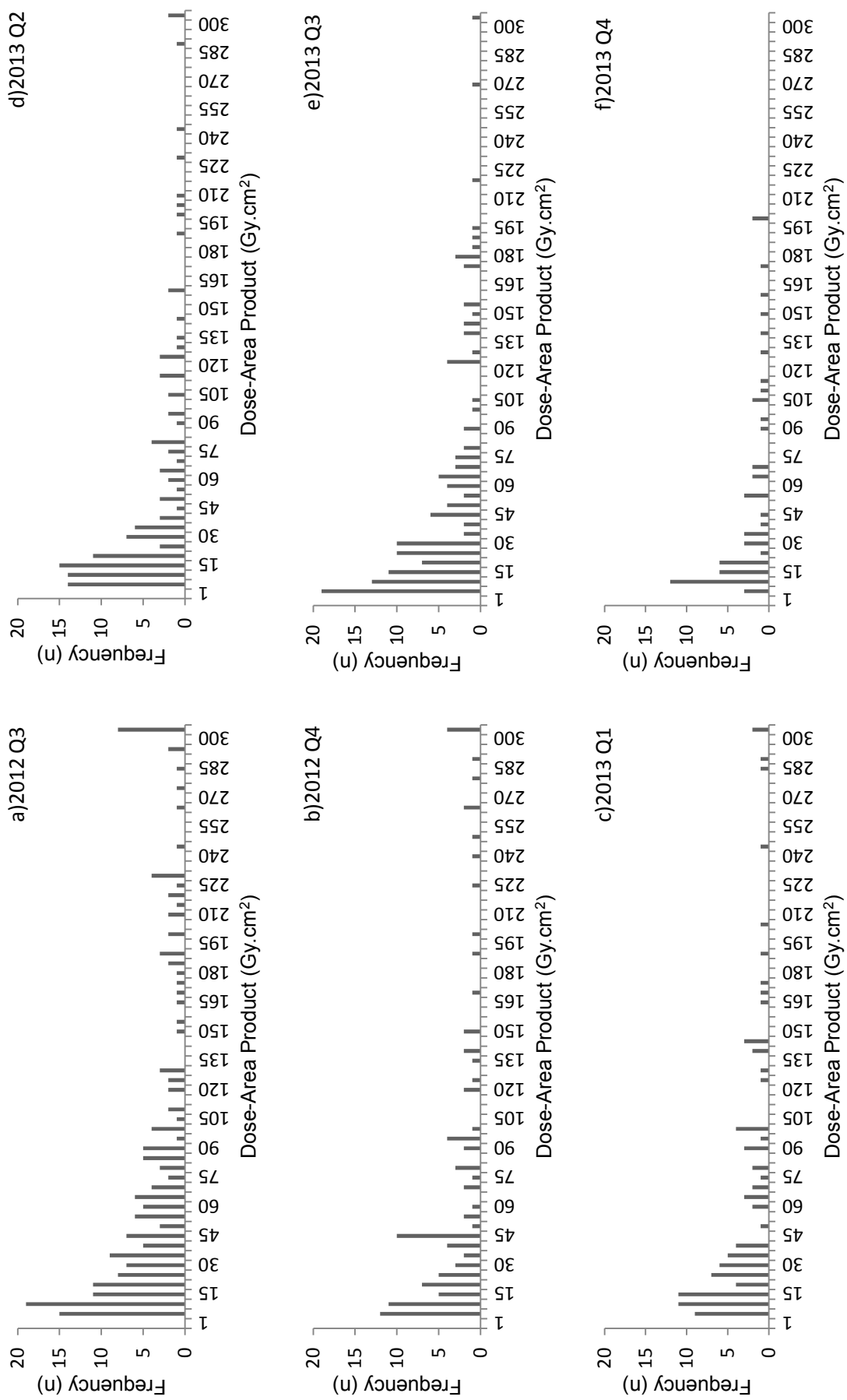


Figure 4.2.6.1 (a-f): Histograms of RF Ablation DAP readings displayed for quarter (a) 2012 Q3, (b) 2012 Q4, (c) 2013 Q1, (d) 2013 Q2, (e) 2013 Q3 and (f) 2013 Q4. The frequency (n) shows the amount of procedures recorded at different DAP levels (Gy.cm<sup>2</sup>).

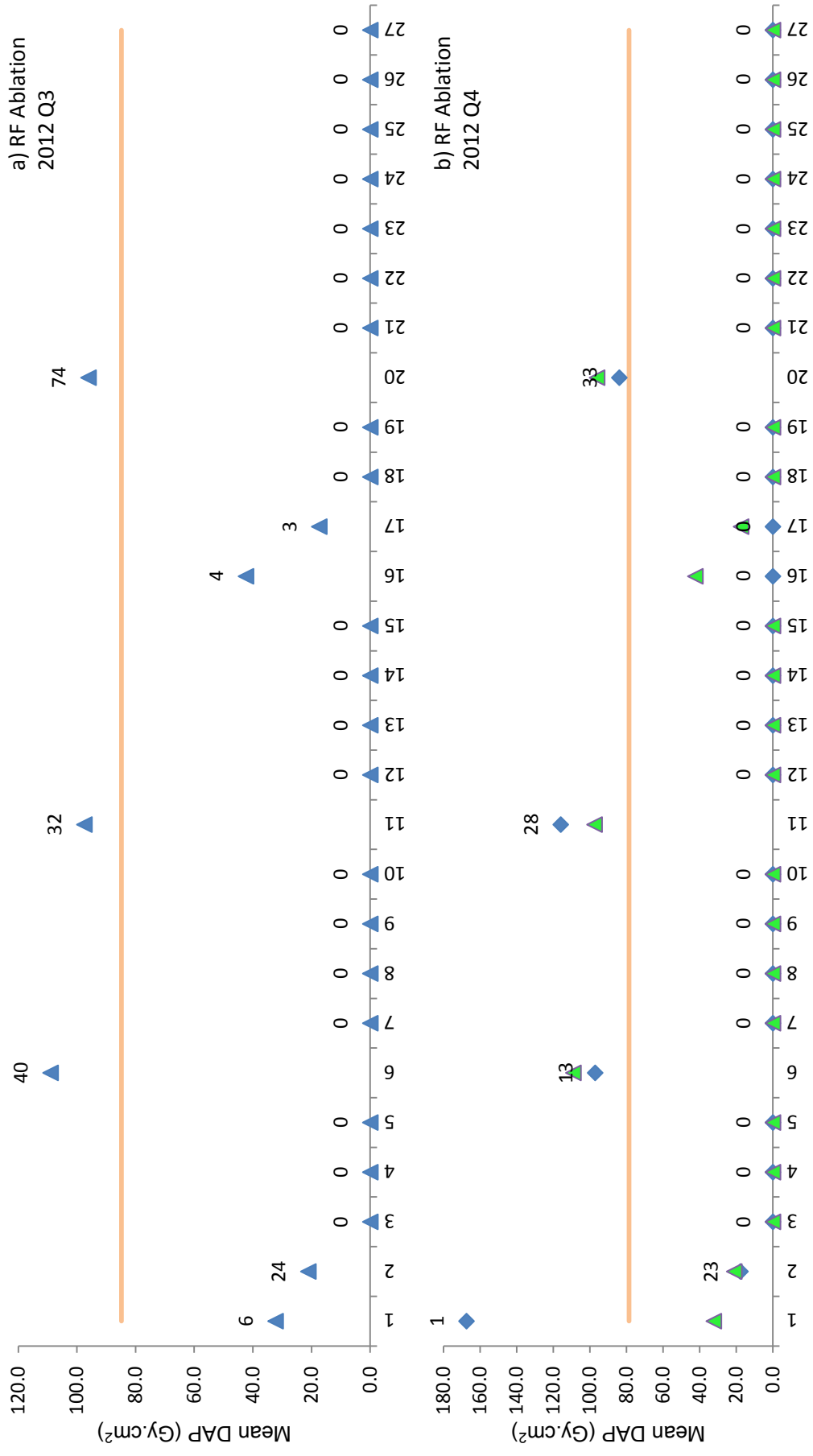


Figure 4.2.6.2 (a-b): Mean RF Ablation DAP readings displayed per theatre (x-axis) as recorded for (a) 2012 Q3 and (b) 2012 Q4. The triangles (▲) indicate baseline values recorded in Q3 2012 and the diamonds (◆) indicate readings for the respective period. The data labels indicate, per theater, the number of cases recorded. The horizontal line represents the mean DAP for all cases.

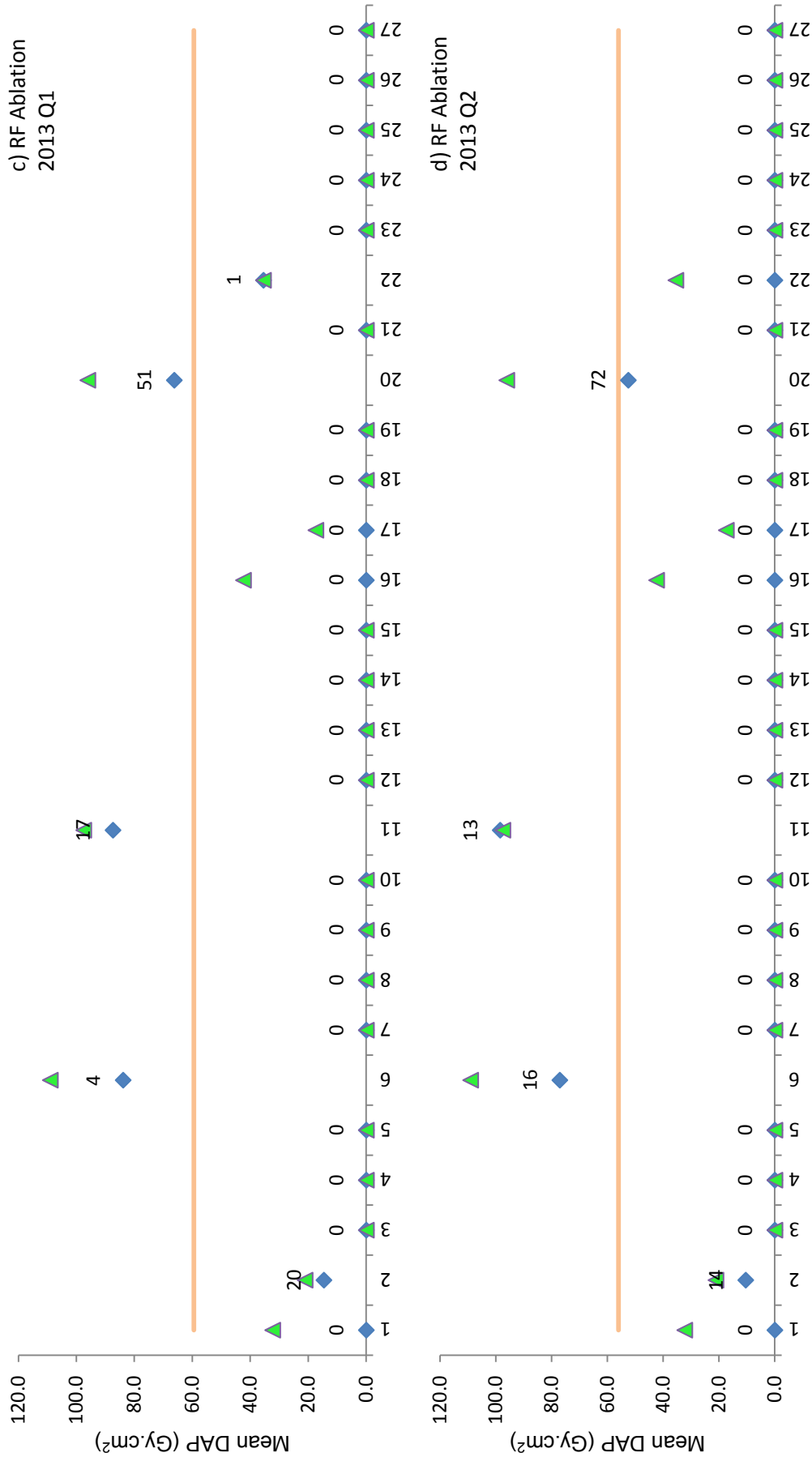


Figure 4.2.6.3 (c-d): Mean RF Ablation DAP readings displayed per theatre (x-axis) as recorded for (c) 2013 Q1 and (d) 2013 Q2. The triangles (▲) indicate baseline values recorded in 2012 Q3 and the diamonds (◆) indicate readings for the respective period. The data labels indicate, per theater, the number of cases recorded. The horizontal line represents the mean DAP for all cases.

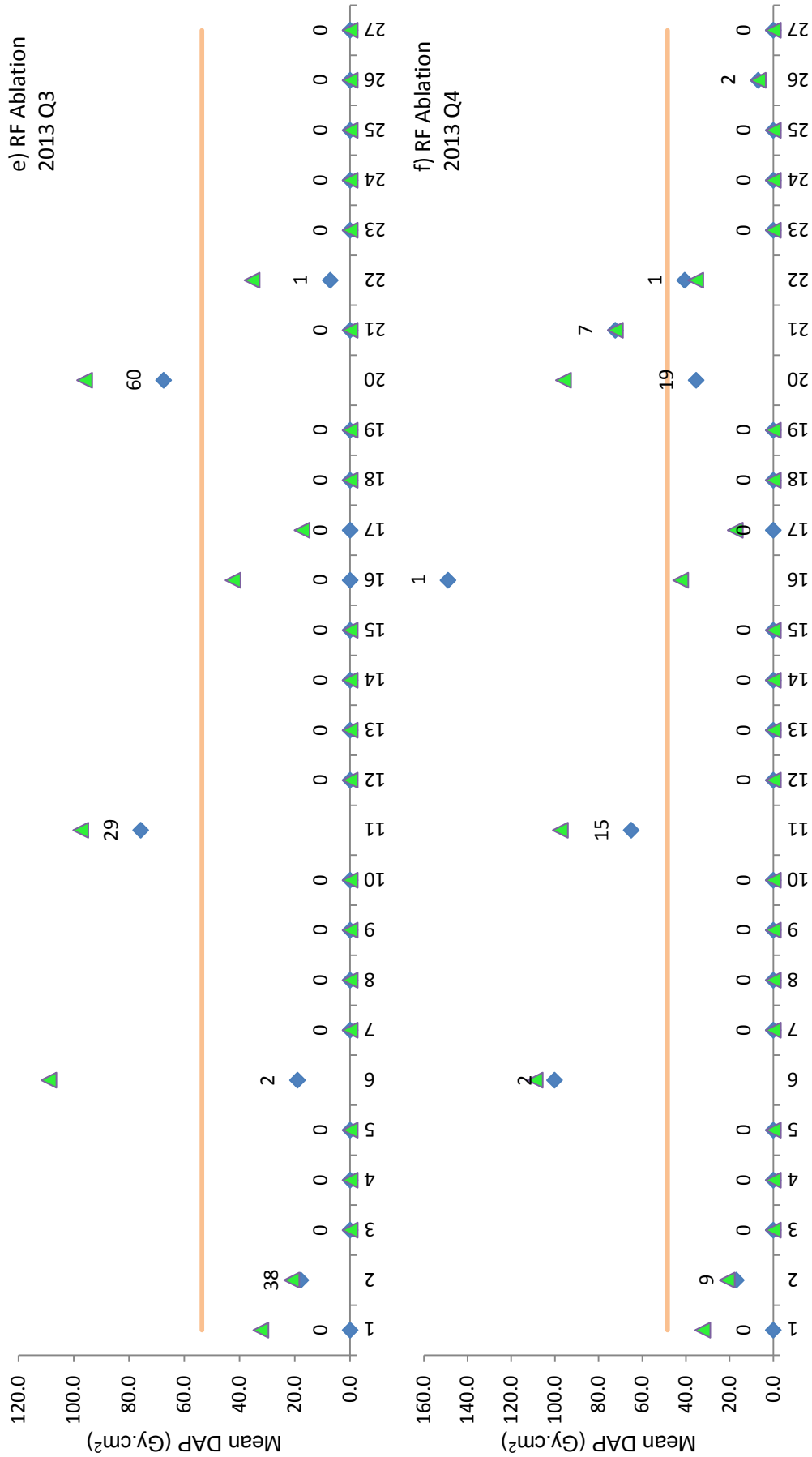


Figure 4.2.6.4 (e-f): Mean RF Ablation DAP readings displayed per theatre (x-axis) as recorded for (e) 2013 Q3 and (f) 2013 Q4. The triangles (▲) indicate baseline values recorded in 2012 Q3 and the diamonds (◆) indicate readings for the respective period. The data labels indicate, per theatre, the number of cases recorded. The horizontal line represents the mean DAP for all cases.

### 4.3 Six Procedure Averages

The mean DAP readings for the six procedures identified for further investigation is shown in figure 4.3.1. This graph, for most procedure types, shows that mean DAP values lowered during the six quarters evaluated.

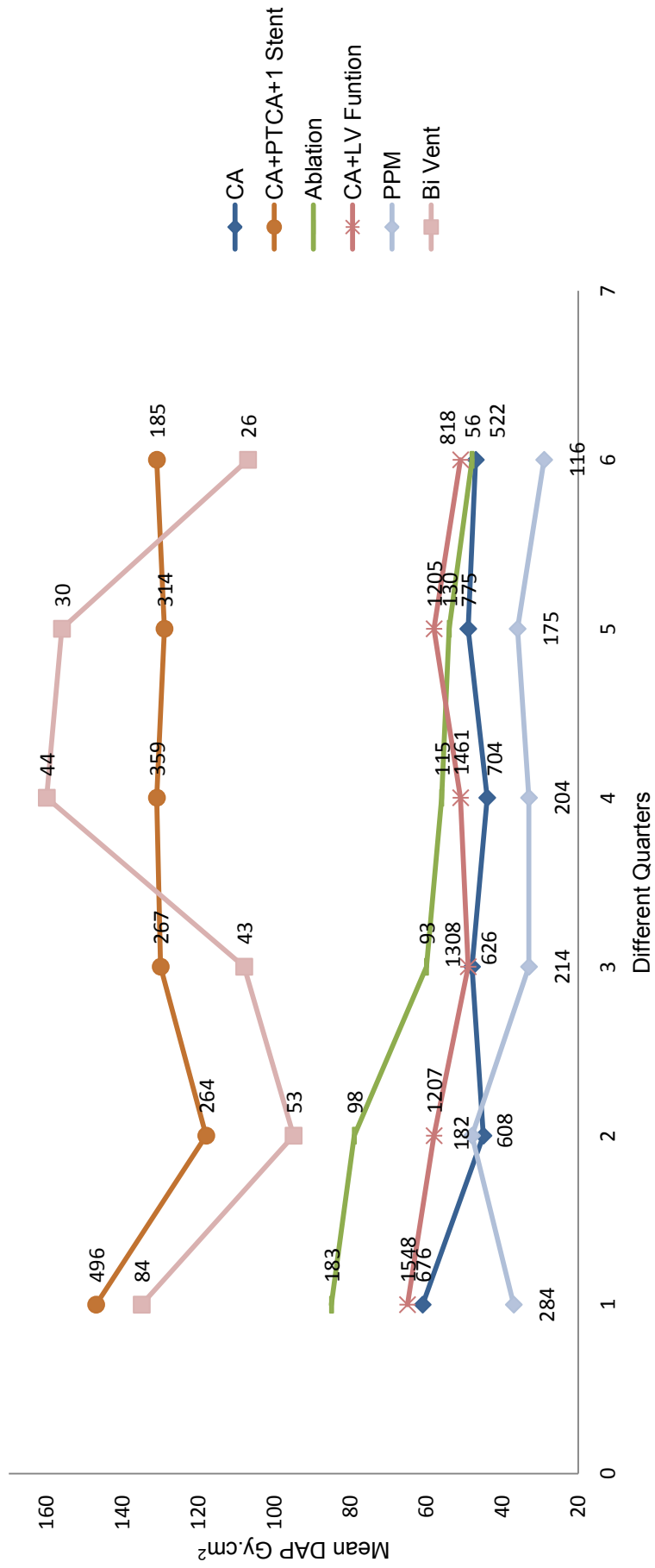


Figure 4.3.1: Mean DAP reading for all theatres shown starting at 2012 Q3 (1) through to 2013 Q4 (6). The number inscription next to each data point indicates the amount of procedures recorded.

## 4.4 Radiation Dose Optimization

### 4.4.1 Null Hypothesis - First Part

The first part of the null hypothesis aimed to determine if the DRL calculated per procedure is higher compared to international levels. The mean international level ( $\pm 1$  SD) was proposed to evaluate this hypothesis. Should the DRLs in this study fall within a range of the international DRL mean ( $\pm 1$  SD), then this should prove that local reference levels are not high in comparison. If DRLs fall outside, or are higher than, the range of international DRLs mean ( $\pm 1$  SD) this would show that local doses are elevated compared to international levels.

Table 4.4.1.1 shows the reference levels of various international studies. These levels are mostly 3<sup>rd</sup> quartile values. Where some authors only disclosed the mean DRL values they were used. The literature review portrayed wide variation in published DRLs for the different procedures which was confirmed by the SD of most procedures investigated. In Table 4.4.1.1 the international mean is the average of the published levels displayed per procedure type. The international mean + 1 SD is the international mean value with the addition of one SD calculated for the range found in these different publications. The SD for Biventricular PPM could not be calculated because only a single international reference was found.

Table 4.4.1.1: The comparison of South African reference levels with the mean of international levels. Listed in this table are various international reference levels, the international mean ( $M_{int}$ ), Standard Deviation (SD) and the international mean (+ 1 SD). First  $H_0$  indicates whether the first part of the null hypothesis. The DRLs listed are in units of Gy.cm<sup>2</sup>.

	CA	CA + LV	CA + PTCA + 1 Stent	PPM	Bi-vent PPM	Ablation
49	Len <i>et al.</i> (112)	41 (Kocinaj <i>et al.</i> ) (113)	154 (Larrazet <i>et al.</i> ) (114)	43 (Makosa & Conradie) (81)	48 (Perisinakis <i>et al.</i> ) (115)	35 (Padovani <i>et al.</i> ) (63)
83	Miller <i>et al.</i> (64)	70 (Padovani <i>et al.</i> ) (68)	199 (Miller <i>et al.</i> ) (64)	21 (D'Heft (116)		140 (Aroua <i>et al.</i> ) (97)
32	Brnić <i>et al.</i> (117)		138 (Multinational) (118)	11 (Perisinakis <i>et al.</i> ) (115)		110 (Chida <i>et al.</i> ) (62)
42	D'Heft <i>et al.</i> (116)		80 (Dragusin <i>et al.</i> ) (48)	38 (Aroua <i>et al.</i> ) (97)		47 (Dragusin <i>et al.</i> ) (48)
71	Bogaert <i>et al.</i> (119)		107 (D'Heft <i>et al.</i> ) (116)			123 (McFadden <i>et al.</i> ) (120)
45	Padovani <i>et al.</i> (63)		206 (Aroua <i>et al.</i> ) (97)			
80	Aroua <i>et al.</i> (97)		149 (Chida <i>et al.</i> ) (62)			
40	Dragusin (48)					
57	Neofotistou <i>et al.</i> (30)					
63	Fransson <i>et al.</i> (121)					
$M_{int}$	56.2	55.5	147.6	28.3	48.0	91.0
SD	17.6	20.5	45.5	14.9	NA	47.1
$M_{int} + SD$	73.8	76.0	193.0	43.1	NA	138.1
This study	57.0	63.0	176.0	36.0	117.0	66.0
	<	<	<	<	?	<

## 4.4.2 Null Hypothesis - Second Part

The second part of the null hypothesis aimed to evaluate if optimization of radiation usage was improved or not. The amount of optimization was investigated and expressed as a percentage change in the 3<sup>rd</sup> quartile DRL per quarter in Table 4.4.2.1. The percentage change shown in this table is expressed as a percentage difference for each quarter compared to the baselines set in Q3 2012.

Table 4.4.2.1: The amount of optimization expressed as a percentage of the baseline 3<sup>rd</sup> quartile DRL values for each of the six procedures investigated. The symbol (↓) indicates the 3<sup>rd</sup> quartile value has reduced compared to baseline, whereas the symbol (↑) indicates it has increased.

	<b>Baseline 2012 Q3 (Gy.cm<sup>2</sup>)</b>	<b>2012 Q4 (%)</b>	<b>2013 Q1 (%)</b>	<b>2013 Q2 (%)</b>	<b>2013 Q3 (%)</b>	<b>2013 Q4 (%)</b>
CA	66	↓15	↓3	↓20	↓13	↓13
CA+LV	77	↓13	↓18	↓14	↓6	↓18
CA+PTCA+ 1 Stent	192	↓18	↓13	↓15	↓7	↓9
PPM	41	↑12	↑5	↑4	↑4	↓13
Bi-vent PPM	144	↓44	↑4	↑56	↑31	↓19
Ablation	104	↓22	↓29	↓38	↓44	↓45

Another important measure of the second hypothesis is proving that a sufficient degree of statistical significance exists to support the optimization calculated. As explained in the method the t-test, proposed for evaluation, is only useful for normal distributions. It is clear in section 4.2 that all the DRL graphs are not normally distributed and the t-test cannot be applied. The logarithm base 10 ( $\text{Log}_{10}$ ) of the DAP data may correct the distributions for the purpose of t-test compliance. Should the  $\text{Log}_{10}$  of the distribution indicate normality then the t-test can be used for the evaluation of the null hypothesis.

The  $\text{Log}_{10}$  was applied to the data and the amount of normality was assessed using a normal probability plot shown in Figures 4.4.2.1-2. The normal probability plot was prepared using the method described by Middelton (110). The method requires that the  $\text{Log}_{10}$  DAP data be sorted in ascending order and plotted on the y-axis vs. the normality score on the x-axis as shown in Figures 4.4.2.1-2. In these graphs the normality score is used to estimate the position of each  $\text{Log}_{10}$  DAP value in relation to the ideal location of a standard normal distribution. If the normal probability plot can be adequately fitted with a linear curve, then the data is normally distributed and the t-test suitable.

The  $\text{Log}_{10}$  of the DAP data does normalize the distribution as indicated in the normal distribution probability graphs. The R2 value for all six procedures was  $> 0.95$  which indicate a good linear fit.

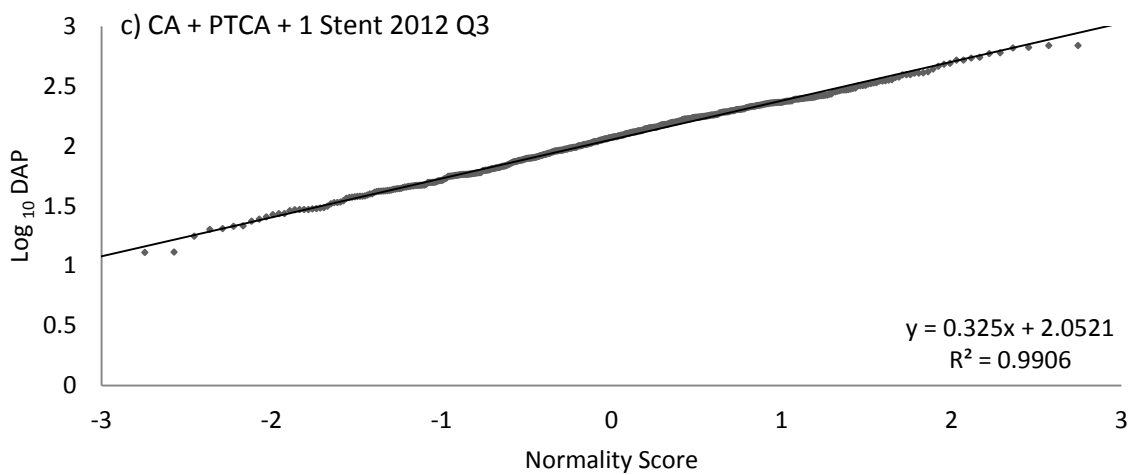
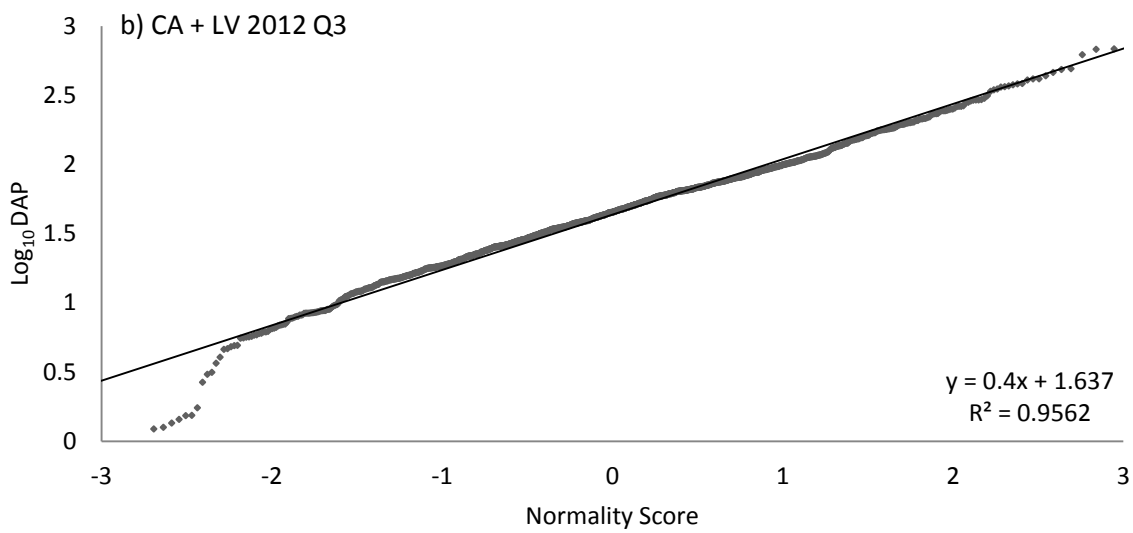
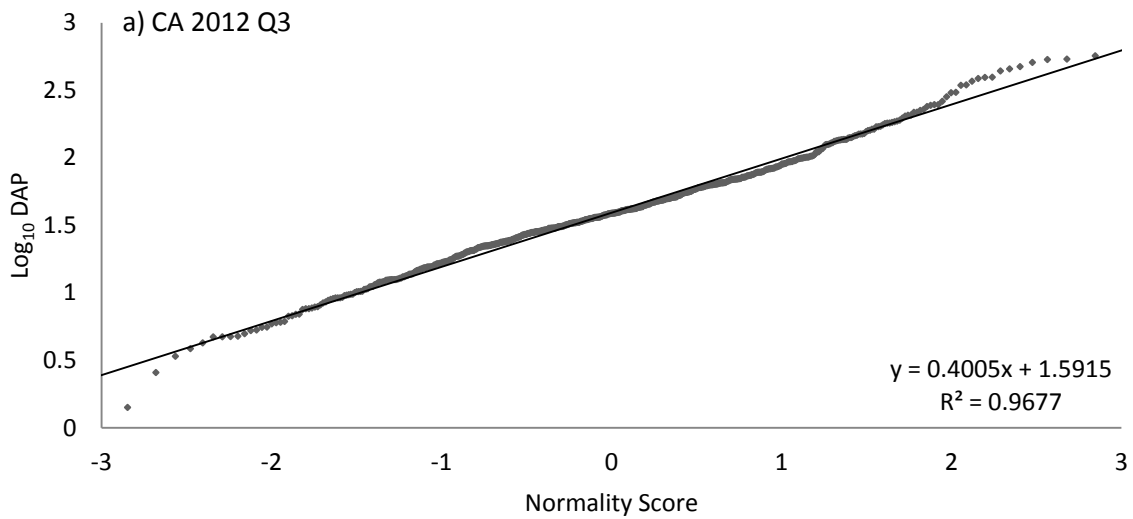


Figure 4.4.2.1 (a-c): The normal distribution probability graphs for (a) CA, (b) CA + LV and (c) CA + PTCA + 1 Stent.

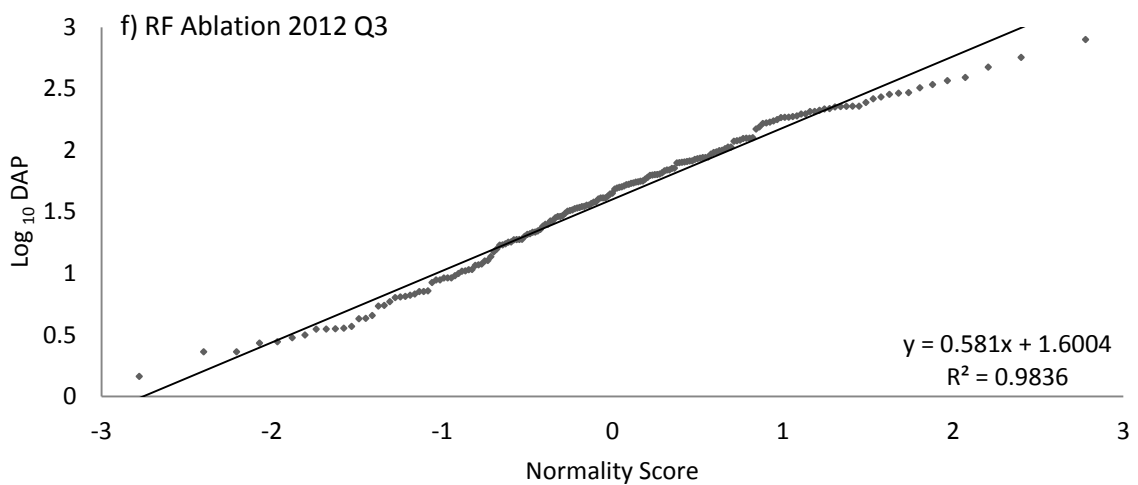
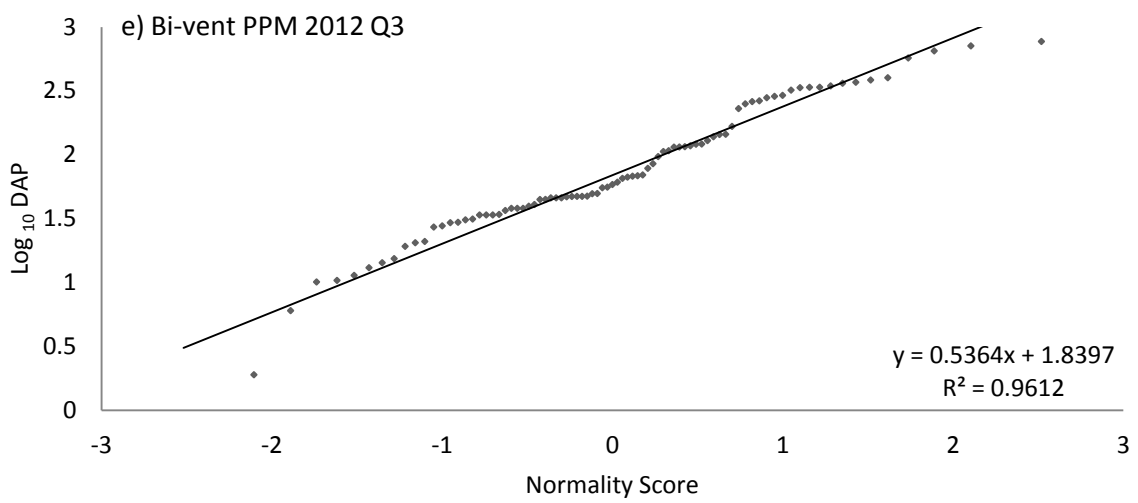
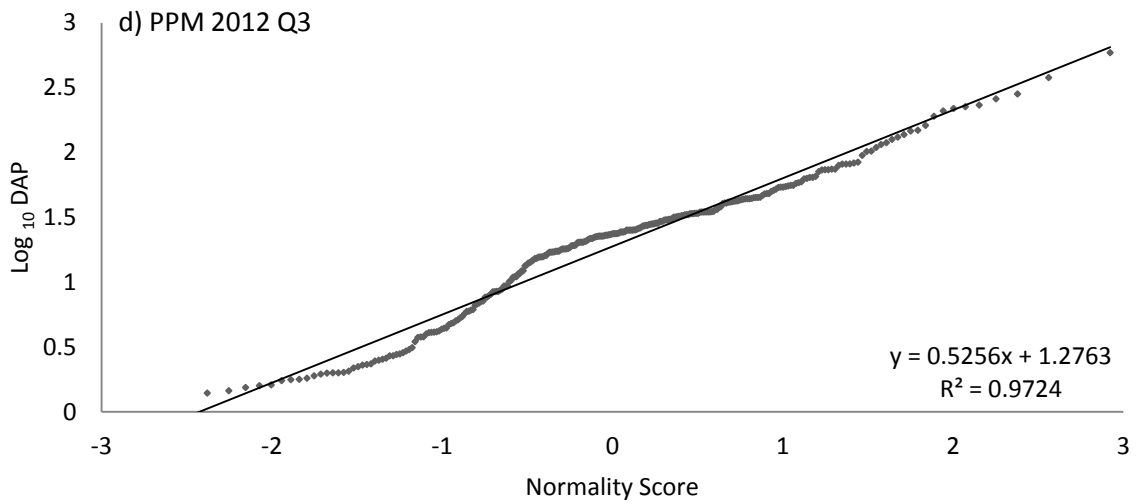


Figure 4.4.2.2 (d-f): The normal distribution probability graphs for (d) PPM, (e) Bi-vent PPM and (f) RF Ablation.

Since the  $\text{Log}_{10}$  DAP data is normally distributed, the t-test may be applied. The t-test checks whether the mean of two samples is significantly different. The two tailed t-test is the more stringent one and is recommended when there is no certainty if the change is one directional.(122)

The output of the two-tailed t-test is in terms of a T statistic ( $T_{\text{stat}}$ ), T critical statistic ( $T_{\text{crit}}$ ) and the Probability value (P). The  $T_{\text{stat}}$  and the  $T_{\text{crit}}$  are test statistical values in units of standard error that measure the difference between and observed statistic and its hypothesised parameter. If the  $T_{\text{stat}}$  is larger in value than the  $T_{\text{crit}}$  the hypothesis may be rejected which would mean, for this study, that optimization was enhanced.

The P-values describe statistical significance and generally a P-value smaller than 0.05 is accepted as being statistically significant. (122) The Alpha value, also known as the significance level, was set to 0.05 for all the t-test performed. This allows a 5% risk of a false positive result using the P-value calculation. A P-value of less than 0.05 would reject the hypothesis and show that optimization was improved. Should the P-value exceed 0.05 the hypothesis cannot be rejected which indicates that statistically no optimization can be confirmed.

Table 4.4.2.2: The results of the individual samples t-test performed on the Log<sub>10</sub> of DAP values for the distributions of each procedure type. For each of the six procedures investigated the hypothesized difference in mean, T statistic, critical T statistic, Probability value (P) and the alpha (α) value is shown. The symbol (↓) indicates the 3<sup>rd</sup> quartile value has reduced from the baseline value.

	% DRL	<i>Second H<sub>0</sub></i> <i>= M<sub>1</sub> - M<sub>2</sub></i>	T <sub>Stat</sub>	T <sub>Crit</sub>	P	α	Reject <i>Second H<sub>0</sub></i>
CA	↓13	0	3.57	1.96	0.0004	0.05	Yes
CA + LV	↓18	0	3.56	1.96	0.0004	0.05	Yes
CA + PTCA + 1 Stent	↓9	0	2	1.97	0.0470	0.05	Yes
PPM	↓13	0	2.08	1.97	0.0388	0.05	Yes
Bi-vent PPM	↓19	0	0.89	2.02	0.3788	0.05	No
Ablation	↓45	0	2.33	1.98	0.0217	0.05	Yes

## CHAPTER 5 DISCUSSION

Table 4.1.1 shows the DAP calibration factors used for all x-ray machines during the investigation period. For most machines the calibration factors had little influence in the resulting mean doses, but for some units the DAP calibration factors change their doses with more than 10% for some months. These units include theatre numbers 1, 4, 7, 19, 22, 25 and 26. When calibration correction factors changed during the course of the investigation, they were updated in the calculation spread sheets for the months following the quality control where the new factor was calculated. The mean DAP calibration correction factor for all x-ray units during all six quarters was 1.02 ( $\pm 0.1$ ).

The DAP readings were collected and evaluated for the six quarters and the amount and mean DAP values per procedures is shown in Table 4.2.1. In total 20415 procedures were recorded from June 2012 – December 2013. The procedures with high incidence that were chosen for detailed evaluation were CA (n = 3911), CA + LV (n = 7547), CA + PTCA + 1 Stent (n = 1885), PPM (n = 1175), biventricular PPM (n = 280) cases and Radiofrequency Ablation (n = 675). These six procedures accounted for 76% of the total number of procedures recorded and thus is an adequate sample to investigate in detail.

Biventricular PPM, despite the lowest incidence in the selection, was also included for detailed evaluation alongside the normal PPM placement. The literature review indicated limited information available regarding biventricular PPM, and the inclusion and comparison of PPM with biventricular PPM may be worthwhile investigating.

A high number of CA + LV + PTCA + Stent procedures were also done during this period. The CA + LV + PTCA + Stent data included many variables and was further divided during the course of the study depending on the amount of stents. This change in procedure description obviously voided the usefulness of the baseline and thus CA + LV + PTCA + 1, 2, 3 Stent were excluded from the six procedures selected for detailed evaluation.

## 5.1 CA

CA was one of the procedures selected for detailed analysis and Table 4.2.1.1 shows the case number, mean, standard deviation and different quartiles of the CA DAP distribution for all six quarters. A total of 3911 CA procedures were included and Table 4.2.1.1 and the mean values were 61, 45, 48, 44, 49, and 47 Gy.cm<sup>2</sup> for the quarters starting at Q3 2012 up to Q4 2013. The calculated DRLs for the same period were 66, 56, 64, 53, 58 and 57 Gy.cm<sup>2</sup>.

The DRL histograms for CA are shown in Figure 4.2.1.1 and clearly have a positively skewed distribution toward the higher dose bins. As confirmed during the literature review, this is the expected distribution for interventional DRL histograms. (64) The shape of the DRL histogram curve appears similar for all six quarters, but with less frequency in high dose components and a slight movement of the curve toward lower dose bins were noticed. This movement, seen graphically, is consistent with the reduction in 3<sup>rd</sup> quartile DRL values seen in Table 4.2.1.1. The number of incident level doses, of larger than 300 Gy.cm<sup>2</sup>, recorded for CA reduced from 16 to 6, 4, 2, 7 and 3 during the six quarters starting at Q3 2012 up to Q4 2013.

During the six quarters for CA it is clear that the standard deviation and inter-quartile range reduced. This is shown in the last rows of Table 4.2.1.1. The SD reduced from 76 to 48 Gy.cm<sup>2</sup> and the IQR reduced from 43 to 36 Gy.cm<sup>2</sup>. Initially, graphically, the wider spread of the DAP baseline histogram is apparent in Figure 4.2.1.1 and the larger SD and IQR is consistent with the Figure. The reduction in SD and IQR for CA shows that the amount of variation in the dataset decreased during the period of data collection and dose optimization.

The mean CA DAP values for each theatre and for each quarter are shown in Figures 4.2.1.2-4. The dose optimization attempt focussed on theatres where their mean values consistently exceeded the mean value calculated for all participating theatres. This was termed the group mean value and can be seen in Figures 4.2.1.2-4 as the horizontal line.

When evaluating Figures 4.2.1.2 (Q3 & Q4 2012) it is very clear that hospital 12 consistently, and with a large margin, exceeded the group mean value for CA. The mean CA DAP values for theatre 12 were 147 and 151 Gy.cm<sup>2</sup> for Q3 and Q4 2012. In the same period the group mean DAP values for CA were 61 and 45 Gy.cm<sup>2</sup>, which is much lower. It was soon realised that the high mean doses recorded for CA procedures at theatre 12 for Q3 & Q4 2012 were unfortunately not isolated to only CA procedures.

The CA + LV procedures for theatre 12 also showed that their mean doses were significantly elevated compared to the group mean. This is illustrated in Figure 4.2.2.2. The mean CA + LV DAP values for theatre 12 were 122 and 129 Gy.cm<sup>2</sup> for Q3 and Q4 2012 and in the same period the group mean DAP values were 65 and 58 Gy.cm<sup>2</sup>.

The other procedures followed suit and theatre 12's doses for CA+PTCA+1 Stent and PPM procedures seen in Figures 4.2.3.2 and 4.2.4.2 are high compared to each respective group mean DAP level. Theatre 12 didn't perform many biventricular pacemakers or radiofrequency ablation procedures.

This high dose trend observed for theatre 12 was a matter of concern to the responsible medical physicist. Closer investigation into the radiographic technique and appointments with each of the radiographers highlighted that the resident cardiologists only use fluorography to perform their cases. This decision to exclusively use fluorography was taken by the cardiologists, because they were not happy with the image quality during normal fluoroscopy screening. The cardiologists motivated this decision, because of the age of the machine and they were not willing to risk making a clinical mistake because of poor image quality. The radiographers knew and advised the cardiologists that this was a high dose technique, but were unsuccessful to cause any changes. The quality control results of the X-ray machine housed in this theatre was reviewed and it showed, despite its age, that the machine was operating within the allowed dose and image quality limits as regulated (17) in South Africa. Poor decisions regarding radiation usage reinforces, for South Africa, the opinion of Vlietstra *et al.* (15), and Koenig *et al.* (3), that there is a lack of radiation safety training among specialists like cardiologists.

The poor radiographic technique explained the high doses recorded in theatre 12. Immediately, upon this realisation, this was addressed with the hospital administrators, cardiologists and radiographers. Firm instruction from the private medical physicists regarding dose reduction was given and this was supported by the hospital administrators and radiographers. The cardiologists were unhappy with

this instruction and emphasized that the problem is not their technique, but equipment related.

The instructions detailed that fluorography should not be used routinely for screening purposes, but only when essential and when image recording is required.

Additionally, multiple radiation optimization and safety training sessions were held for the radiographers and theatre staff. The IAEA optimization posters (101) were also explained and distributed during these training sessions.

The balance between image quality and dose was highlighted here. If specialists are untrained on the concept of dose, they lean towards achieving the best image quality. During the SAAPMB 2007 opening session Gray (77) said, “Noise is good” and, “As long as dose is good and image quality is good, I am not worried about other factors like mA, kV, filtration, etc.” To these doctors the concept of “noise is good” was unfamiliar and hard to accept.

The correction of this poor technique and the optimization training resulted in theatre 12’s mean CA dose being reduced by 44% and CA +LV by 34% from baseline mean doses in Q4 2013. This was encouraging, that even for ageing technology and for largely un-cooperating specialists, dose optimization seemed to eventually lower doses. The radiation incident investigations and management assisted with dose optimization, especially for theatre 12, because the responsible medical physicist was often consulted to help maintain radiation dose awareness.

## 5.2 CA + LV

Another procedure analysed in detail is the 7547 CA + LV cases recorded. Table 4.2.2.1 show the amount of CA+LV cases, mean, standard deviation and different quartiles for the CA + LV distribution for all six quarters. CA + LV showed a reduction of mean DAP and a reduction in 3<sup>rd</sup> quartile DRL from 65 to 51 Gy.cm<sup>2</sup> and from 77 to 63 Gy.cm<sup>2</sup> respectively. The SD and IQR for CA + LV decreased from 71 to 48 Gy.cm<sup>2</sup> and from 51 to 38 Gy.cm<sup>2</sup> respectively. This is similar to the trend observed for CA procedures without LV function tests included.

The CA + LV DRL histograms in Figure 4.2.2.1 also show a positively skewed distribution, as with CA. The reduction in mean, DRL, SD and IQR is reinforced by the slight movement of the distribution graphs towards lower dose bins. The number of incident level doses of larger than 300 Gy.cm<sup>2</sup>, recorded for CA + LV reduced from 22 to 16, 7, 3, 8 and 4 during the six quarters starting at Q3 2012 up to Q4 2013.

The mean CA + LV DAP values for each theatre and for each quarter are shown in Figures 4.2.2.2-4. On Figure 4.2.2.2 (a) the baseline CA + LV values are shown. In this Figure theatres 12, 15 and 22 had mean doses that were considerably higher than the group mean. High doses for theatre 12 CA + LV have been discussed. Theatre 15 recorded their baseline CA + LV mean DAP as 185 Gy.cm<sup>2</sup>. During the other quarters their CA + LV dose ranged between 22 – 43 Gy.cm<sup>2</sup>, which is better than and surely comparable to the group mean CA + LV DAP. This high baseline for theatre 15 may be attributed to the sad passing on of one of the hospital's cardiologists, which resulted in a young doctor taking over his case load. These may be indicative of the new cardiologist becoming familiar with the theatre and local

procedures. Theatre 22 is a combined cardiac and vascular unit which does not perform many cardiology cases. This is probably the reason for the high CA + LV baseline, as cardiology is not their clinical forte.

Considering that CA+LV is the normal CA procedure, which includes ventriculography, where typically ejection fraction, stroke volume and cardiac output is measured, it can be expected to have a higher mean dose than CA alone. The literature review found very few articles differentiating between CA with and without the inclusion of LV. Fazel *et al.* (123) described diagnostic CA and resting heart LV quantification as both being medical procedures that have a large contribution to populations' effective doses. Padovani *et al.* (68) published a CA reference level with LV function included of 70 Gy.cm<sup>2</sup>. This is marginally higher than our Q4 2014 DRL for CA+LV of 63 Gy.cm<sup>2</sup>.

The reference level calculated for both baseline and current data indicates that the addition of LV function increases the dose needed compared to a normal CA. This was consistent for all quarters: the observed CA + LV mean DAP was higher than that of CA only. Respectively, for the 6 quarters, the mean DAP value of CA + LV was 3.9, 12.8, 0.8, 7.4, 8.5 and 4.1 Gy.cm<sup>2</sup> higher than that of CA. This is shown graphically in Figure 4.3.1.

On average the mean CA + LV DAP was 6.3 Gy.cm<sup>2</sup> higher than CA and the 3<sup>rd</sup> quartile DRL was on average 9.2 Gy.cm<sup>2</sup> higher. Clark *et al.* (124) noted that they found, in their study of 1337 cardiac procedures, that LV function increased CA mean doses by an average of 6 Gy.cm<sup>2</sup>. This was attributed to the extra screening required to perform the ventricle tests like ejection fraction, stroke volume and cardiac output. The results of Clark *et al.* (124) noting the difference in CA and CA + LV are consistent with this study.

### 5.3 CA + PTCA + 1 Stent

CA + PTCA + 1 Stent was also selected for detailed analysis and Table 4.2.3.1 shows the case number, mean, standard deviation and different quartiles of the distribution of all six quarters. A total of 1885 CA + PTCA + 1 Stent procedures were included and in Table 4.2.3.1 the mean dose values were 147, 118, 130, 131, 130, and 137 Gy.cm<sup>2</sup> for the quarters starting at Q3 2012, up to Q4 2013. The calculated DRLs for the same period were 192, 157, 167, 164, 179 and 176 Gy.cm<sup>2</sup>.

The DRL histograms for CA + PTCA + 1 Stent are shown in Figure 4.2.3.1 and do not appear as neatly positively skewed compared to the distributions of CA and CA + LV. This is likely because the procedure includes larger variations in complexity and difficulty. The variation is quantified using the SD and IQR shown in Table 4.2.3.1. The CA + PTCA + 1 Stent mean SD and IQR for the six quarters are 105 Gy.cm<sup>2</sup> and 112 Gy.cm<sup>2</sup> respectively. These variation quantifiers are more than double those of CA and CA + LV procedures.

The shape of the DRL histogram curve appears similar for all six quarters and graphically no lower dose shift in the distribution is apparent. The number of incident level doses of larger than 300 Gy.cm<sup>2</sup>, recorded for CA+ PTCA + 1 Stent reduced from 39 to 14, 23, 22, 20 and 14 during the six quarters starting at Q3 2012 up to Q4 2013. The mean DAP and 3<sup>rd</sup> quartile reduced from 147 to 137 Gy.cm<sup>2</sup> and from 192 to 175 Gy.cm<sup>2</sup>. The SD and IQR remained high and quite stagnant for the six quarters analysed despite the optimization attempts. The slow reaction of the SD and IQR variation quantifiers may be a result of the wide variation in complexity of these cases.

Larrazet *et al.* (114) noted the wide variation in complexity of PTCA procedures and evaluated the operator's and technique dependence. They found that mean DAP for PTCA and stenting was highly dependent on the operator and on the technique used by the cardiologist. Operator and technique differences in this study may be attributing to the large SD and IQR seen.

The CA + LV + PTCA + 1, 2, 3 Stent procedures were not evaluated in detail like the above CA + PTCA + 1 Stent cases but still holds valuable information. Investigation of the mean DAP results displayed in Table 4.2.1 shows that DAP readings increase when additional stents are placed. When more stents are used during a procedure it clearly resulted in higher mean exposure values to the patient. This trend was consistent for all the quarters shown in Table 4.2.1. The last quarter of this work, 2013 Q4, shows the mean result for CA + LV + PTCA + 1 Stent (131 Gy.cm<sup>2</sup>), 2 Stents (145 Gy.cm<sup>2</sup>) and 3 Stents (148 Gy.cm<sup>2</sup>).

## **5.4 PPM & Biventricular PPM**

The pacemaker placement procedures included PPM and biventricular PPM. There were 1175 PPM and 280 Biventricular PPM cases recorded. Table 4.2.4.1 and Table 4.2.5.1 show the amount, mean, standard deviation and different quartiles for the two pacemaker procedure distributions for all six quarters. PPM showed a reduction of mean DAP and a reduction in 3<sup>rd</sup> quartile DRL from 37 to 29 Gy.cm<sup>2</sup> and from 41 to 36 Gy.cm<sup>2</sup>. The SD and IQR, for PPM, decreased from 67 to 34 Gy.cm<sup>2</sup> and from 32 to 31 Gy.cm<sup>2</sup>.

The PPM DRL histograms in Figure 4.2.4.1, showed again a neatly positively skewed distribution. The reduction in mean, DRL, SD and IQR is reinforced by the slight movement of the distribution graphs towards lower dose bins. This is similar to the trend observed for CA and CA + LV. The number of incident level doses recorded was very low in comparison to the other procedures analysed as only 9 out of the 1175 cases breached the 300 Gy.cm<sup>2</sup> investigation level.

The 3<sup>rd</sup> quartile reference level determined for PPM was the lowest of all the procedures investigated. The mean PPM DAP values for each theatre and for each quarter are shown in Figures 4.2.4.2-4. As discussed previously, theatre 12 is yet again clearly higher than the group mean level because of their poor radiographic technique.

Biventricular PPM showed a reduction of mean DAP and a reduction in 3<sup>rd</sup> quartile DRL from 135 to 107 Gy.cm<sup>2</sup> and from 144 to 117 Gy.cm<sup>2</sup>. The much higher doses mean doses recorded for biventricular PPM alludes to it being a more complex and variable procedure than normal PPM. As seen in Table 4.2.5.1 the SD and IQR, for biventricular PPM, was quite variable during the six quarters. Q3 2012 compared to Q4 2013 indicates that the SD and IQR decreased from 164 to 125 Gy.cm<sup>2</sup> and from 110 to 92 Gy.cm<sup>2</sup>.

The biventricular PPM DRL histograms in Figure 4.2.5.1 show an untidy and skewed distribution. This histogram and the wide variation in the SD and IQR are similar to the trend observed for CA + PTCA + 1 Stent procedures. The histogram curve appears similar for all six quarters and graphically no lower dose shift or big changes are apparent. The number of incident level doses, of larger than 300 Gy.cm<sup>2</sup>, recorded for biventricular PPM reduced from 13 to 4, 5, 8, 4 and 2 during the six quarters starting at Q3 2012 up to Q4 2013.

The variation in SD and IQR, as seen for the CA + PTCA + 1 Stent, may indicate the complexity of the procedure. The mean SD and IQR for biventricular PPM during this study was 155 and 122 Gy.cm<sup>2</sup>. This is an even higher variation than seen for CA + PTCA + 1 Stent of 105 and 112 Gy.cm<sup>2</sup>. Considering this, it can be alleged that the variation in complexity of biventricular PPM was the highest.

The variation in the mean of biventricular PPM DAP is shown graphically in figure 4.3.1 and the mean biventricular PPM DAP values for each theatre and for each quarter are shown in Figures 4.2.5.2-4. Figures 4.2.5.4 (f) shows that many theatres performed no biventricular PPM procedures during the six quarters. This may be because not all practitioners attempt these complex cases routinely. The graphs seen in Figures 4.2.5.2-4 visually support the high SD and IQR calculated for biventricular PPM.

## **5.5 Radiofrequency Ablation**

The last of the six procedures included for analysis was radiofrequency ablation. This is an electrophysiology procedure, which should be seen as a subspecialty of cardiology requiring additional training. This resulted in not many hospitals performing ablation cases routinely. As seen in Figures 4.2.6.2-4 the most cases were done by theatres 2, 6, 11 and 20.

During this study 675 radiofrequency ablation cases were recorded. Table 4.2.6.1 show the amount, mean, standard deviation and different quartiles for the ablation distribution for all six quarters. RF ablation showed a reduction of mean DAP and a reduction in 3<sup>rd</sup> quartile DRL from 85 to 48 Gy.cm<sup>2</sup> and from 104 to 66 Gy.cm<sup>2</sup>. The

SD and IQR, for RF ablation, decreased from 109 to 53 Gy.cm<sup>2</sup> and from 88 to 57 Gy.cm<sup>2</sup>. This is similar to the trend observed for CA, CA + LV and PPM procedures.

The RF ablation DRL histograms in Figure 4.2.6.1, again show a neatly positively skewed distribution, similarly to the diagnostic procedures and PPM. The reduction in mean, DRL, SD and IQR is reinforced by the reduction in case frequency in the higher dose bins. This is similar to the trend observed for CA, CA + LV and PPM.

The number of incident level doses recorded reduced from 8 during Q3 2012 to 4, 2, 2, 1 and 0 for the other quarters. The mean ablation DAP values for each theatre and for each quarter are shown in Figures 4.2.6.2-4.

Theatre 2 and 20 make use of a robotic catheter navigational system for electrophysiology and for robotic radiofrequency ablation. Lorgat *et al.* (125), one of the surgeons resident at hospital 2, explains in detail the benefits of these remote robotic catheter devices and specifically mentions the reduction in screening time and resulting radiation dose. The mean DAP value calculated for robotic radiofrequency ablation was considerably less than that of normal ablation without the robotic device. The mean DAP for robotic radiofrequency ablation was determined in Q4 2013 as 27 Gy.cm<sup>2</sup>. This is 56 % lower than the mean DAP for normal radiofrequency ablation, which is consistent with the comments made by Lorgat *et al.* (125).

## 5.6 Other Interesting Observations

EVAR procedures consistently accounted for the highest mean DAP values during each quarter of 2013. The mean doses for EVARs recorded for the four quarters in

the last year of this study was 704, 849, 375 and 515 Gy.cm<sup>2</sup>. These are considerably high mean doses when compared to the incident level of 300 Gy.cm<sup>2</sup>. Many of these cases exceeded the incident investigation level, which was of a major concern.

The high mean dose of EVAR procedures is consistent with the fact that these are cumbersome procedures that involve a lot of screening, and was further investigated. In the private hospital group three of the participating theatres contributed > 90% of the EVAR cases. These three theatres were numbered 12, 18 and 25. Theatre 12 recorded mean doses of: 480, 445, 764 and 579 Gy.cm<sup>2</sup> respectively for the four quarters of 2013. Theatre 18 recorded mean doses of: 979, 1024, 309 and 666 Gy.cm<sup>2</sup> respectively for the four quarters of 2013. Theatre 25 recorded mean doses of: 480, 445, 764 and 579 Gy.cm<sup>2</sup> respectively for the four quarters of 2013. These results pointed to theatre number 18 having the highest mean EVAR doses. Additionally they also did the most EVAR procedures and account for > 50% of the total EVAR cases.

Following the first EVAR results in Q1 2013, closer investigation of the practise and radiological technique used in theatre 18 showed high usage of high pulse rate fluorography and high dose fluoroscopy during EVAR cases. The EVAR cases in theatre 18 were exclusively performed by the vascular surgeons' resident at the hospital. They mentioned, in consultation with the responsible medical physicists, that they perform highly complex cases and have become a referral centre for complex vascular work. Initial communication with these doctors was difficult and hospital administrators had to become involved to ensure all parties participated in optimization attempts.

During the last months of Q2 2013 the fluorography technique factors on the x-ray machine were adjusted and the lowest frame-rate that doctors would accept was 7.5 fps for EVAR cases. Additionally to the EVAR fluorography adjustment, the default fluoroscopy setting on the unit was set to low dose. The IAEA optimization posters (101) were distributed and radiation protection training was given to radiographers, vascular surgeons and staff.

Incident management added value to the optimization attempt, because most of the EVAR cases resulted in incidents. Part of the investigation into the high EVAR dose phenomenon involved consultation with other medical physicist teams (126) experienced in radiology. They (126) noted that these doses are likely elevated compared to their local levels and offered valuable advice to aid in optimization.

It was found that, for the sake of incident investigation that the level of  $300 \text{ Gy.cm}^2$  is, in all likelihood, too low for typical EVAR cases because the field size is typically much larger than  $100 \text{ cm}^2$ . The responsible medical physicist attempted to reproduce work done by Delle *et al.* (127) and measure the field size using Gafchromic film, but it was largely unsuccessful because of the amount of movements during EVAR procedures, not allowing accurate field visualization.

The likelihood of field sizes exceeding  $100 \text{ cm}^2$  for EVAR was based on the collimator field size and magnification settings during procedures. This means that the peak skin dose is lower than for procedures with smaller field sizes, and an investigation level of  $500 \text{ Gy.cm}^2$  may be more applicable for EVAR cases. This level is recommended by the IAEA SAFRAD (103) incident management system.

Following this Q2 2013 investigation into the EVAR procedure's radiographic technique, the mean doses for theatre 18 reduced to  $309 \text{ Gy.cm}^2$  for 5 cases

performed during 2013 Q3. This reduction in mean dose may be attributed to technique changes and active medical physics and hospital administrator involvement with the vascular surgeons performing EVAR cases.

Other vascular procedures supporting the above argument are the 272 peripheral angiograms and 450 peripheral interventions performed during 2013. The mean doses for peripheral angiograms recorded for the four quarters of 2013 was 83, 75, 64 and 52 Gy.cm<sup>2</sup> respectively. Mean doses for peripheral interventions during the same period were 704, 849, 375 and 515 Gy.cm<sup>2</sup> respectively. Theatre number 18 accounted for 16 % of the peripheral angiograms and for 35 % of the peripheral interventions performed in all theatres. During the course of 2013, doses used for peripheral interventions in theatre 18 reduced from 224 Gy.cm<sup>2</sup> (Q1 2013) to 135 Gy.cm<sup>2</sup> (Q2 2013), 93 Gy.cm<sup>2</sup> (Q3 2013) and 81 Gy.cm<sup>2</sup> (Q4 2013). The peripheral angiography procedures followed the same trend and doses reduced from 84 Gy.cm<sup>2</sup> (Q1 2013) to 107 Gy.cm<sup>2</sup> (Q2 2013), 36 Gy.cm<sup>2</sup> (Q3 2013) and 28 Gy.cm<sup>2</sup> (Q4 2013) respectively.

## **5.7 Hypothesis Review**

The first part of the null hypothesis questioned if South African interventional cardiology radiation doses are high in comparison with international levels. Table 4.4.1.1 shows the reference levels determined in this study when compared to available international levels.

The mean international level for CA was calculated as 56.2 Gy.cm<sup>2</sup> with a standard deviation of 17.6 Gy.cm<sup>2</sup>. This resulted in the deciding limit for CA of 73.8 Gy.cm<sup>2</sup>

which is higher than the CA DRL proposed in this work of 57 Gy.cm<sup>2</sup>. This means that South African private healthcare CA interventional levels are not high in comparison with international levels. Applying this same argument to the work done by Miller *et al.* (64) in the United States would mean their CA DRL of 83 Gy.cm<sup>2</sup> is high in comparison to international levels. They conclude in this work that there is room for improvement in the United States and that their doses are not optimized. The work done in Switzerland by Aroua *et al.* (97) proposed a CA DRL of 80 Gy.cm<sup>2</sup> which may also be considered high in comparison.

A similar result was obtained for CA + LV, CA + PTCA + 1 Stent, PPM and RF ablation where the South African private healthcare levels determined in this work was lower than the international mean. The mean international DRL for these procedures in order of mention was 55.5, 147.6, 28.3 and 91 Gy.cm<sup>2</sup>. The SD was 20.5, 45.5, 14.9 and 47.1 Gy.cm<sup>2</sup>. The international mean with one SD added was 76, 193, 43 and 138 Gy.cm<sup>2</sup> which was less than the DRL proposed in this work of 63, 176, 36 and 66 Gy.cm<sup>2</sup>.

Miller *et al.* proposed 199 Gy.cm<sup>2</sup> as a United States DRL for PTCA; this is high in comparison with the international mean calculated of 147.6 Gy.cm<sup>2</sup>. This is consistent with the results of CA which also indicated that doses in the United States are elevated.

As with CA, the DRLs proposed by Aroua *et al.* (97) in Switzerland for PTCA and radiofrequency ablation of 260 and 140 Gy.cm<sup>2</sup> are high in comparison to international mean levels plus one SD of 193 and 138 Gy.cm<sup>2</sup>.

The evaluation of PPM showed that all the international levels fall within this range. Makosa & Conradie (81) proposed initial levels for a public hospital in South Africa of

43 Gy.cm<sup>2</sup>. This proposed level is equal to the international mean plus one SD calculated and shown in Table 4.4.1.1 of this work.

The biventricular PPM posed a problem as only one international DRL could be found which made a SD calculation impossible. The biventricular PPM level of 48 Gy.cm<sup>2</sup> published in Greece by Perisinakis *et al.* (115) was presented as a mean value on a study population of 14 patients. This makes a biventricular PPM comparison with international means not feasible for this work and no comparison result is proposed.

Table 5.1 compares the proposed DRLs in this work with other 3<sup>rd</sup> quartile DRLs published in other countries. Where 3<sup>rd</sup> quartile results were not available in these publications, e.g., for biventricular PPM, the mean DAP value was used. The proposed DRLs compare well with the listed published data.

Table 5.1: Proposed reference levels for the private healthcare sector in South Africa; includes baseline DRLs, amount of optimization and comparison to publications from other countries. The amount of procedures evaluated for each review period (*n*) is indicated below the displayed DRL value.

	<b>Baseline (Gy.cm<sup>2</sup>)</b>	<b>This Study (Gy.cm<sup>2</sup>)</b>	<b>%</b>	<b>International Publications (Gy.cm<sup>2</sup>)</b>
				49 (Aus – Lin <i>et al.</i> 2013) (112)
				83 (USA – Miller <i>et al.</i> 2012) (64)
CA	66 ( <i>n</i> = 676)	57 ( <i>n</i> = 522)	↓13	32 (Croatia – Brnic <i>et al.</i> 2010) (117)
				42 (Ireland – D’Helft <i>et al.</i> 2009) (116)
				71 (Belgium – Bogaert <i>et al.</i> 2008) (119)

				45 (EU – Padovani <i>et al.</i> 2008) (128) 80 (Swiss – Aroua <i>et al.</i> 2007) (97) 40 (Belgium – Dragusin <i>et al.</i> 2005)(48) 57 (Europe – Neofotistou <i>et al.</i> 2003) (30) 63 (Sweden – Fransson <i>et al.</i> 2000) (121)
CA+ LV	77 (n = 1548)	<b>63</b> (n = 818)	↓18	41 (Italy – Kocinaj <i>et al.</i> 2006) (113) 70 (EU – Padovani <i>et al.</i> 1998) (68)
CA+PTCA +STENT	192 (n = 496)	<b>176</b> (n = 185)	↓9	154 (France – Larrazet <i>et al.</i> 2014) (114) 199 (USA – Miller <i>et al.</i> 2012) (64) 138 (Multinational – 2007) (118) 80 (Belgium – Dragusin <i>et al.</i> 2005)(48) 107(Ireland – D’Helft <i>et al.</i> 2009) (116) 260 (Swiss – Aroua <i>et al.</i> 2007) (97) 149 (Japan – Chida <i>et al.</i> 2006) (62)
PPM	41 (n = 284)	<b>36</b> (n = 116)	↓13	43 (SA – Makosa & Conradie 2015) (81) 21 (Ireland - D’Helft <i>et al.</i> 2009) (116) 11 (Greece – Perisinakis <i>et al.</i> 2005) (115) 38 (Swiss – Aroua <i>et al.</i> 2004) (69)
Bi-Vent PPM	144 (n = 84)	<b>117</b> (n = 26)	↓19	48 (Greece – Perisinakis <i>et al.</i> 2005) (115)
RF Ablation	104 (n = 183)	<b>66</b> (n = 56)	↓45	35 (EU – Padovani <i>et al.</i> 2008) (63) 140 (Swiss – Aroua <i>et al.</i> 2007) (97) 110 (Japan – Chida <i>et al.</i> 2006) (62) 47 (Belgium – Dragusin <i>et al.</i> 2005)(48) 123 (Ireland – McFadden <i>et al.</i> 2002) (120)

The baseline DAP reading for CA established in 2012 was 65.9 Gy $\text{cm}^2$  and a total of 676 procedures were used for the initial establishment of the DRL. This value has reduced to 57.1 Gy $\text{cm}^2$  in 2013 and 522 cases were used in its establishment. The baseline for CA+LV was 76.8 Gy $\text{cm}^2$  calculated using 1548 procedures which improved to 63.3 Gy $\text{cm}^2$  calculated using 818 procedures. CA + PTCA, PPM,

biventricular PPM and radiofrequency ablation cases followed a similar trend and improved from 192, 41, 144 and 104 Gy.cm<sup>2</sup> determined from 496, 284, 84 and 183 cases to 176, 36, 117 and 66 Gy.cm<sup>2</sup> for 185, 116, 26 and 56 procedures.

These reductions in DRL translate to a 13% improvement for CA, 18% for CA+LV, 9% for CA + PTCA + 1 Stent, 13% for PPM, 19 % for biventricular PPM and 45% for radiofrequency ablation.

The second part of the null hypothesis focussed on whether dose optimization was improved or not and if the reductions in DRL noted above had statistical significance. The proposed t-test evaluation to prove or disprove the null hypothesis required the data to be normally distributed. Most DAP histograms showed, as expected, a positively skewed distribution. In an attempt to comply with the normal distribution requirements of the t-test the logarithm (base 10) of the DAP values were calculated and reviewed for normality using a normal probability graph.

The normal probability graphs are shown for all six procedures in Figures 4.4.2.1-2. These graphs were fitted using linear equations which resulted in a coefficient of determination value ( $R^2$ ) of 0.97, 0.96, 0.99, 0.97, 0.96 and 0.98 for the six procedures. This is a good fit of the normal probability graphs and means that the  $\text{Log}_{10}$  of the DAP values can be considered a natural distribution which makes the t-test an appropriate statistical tool to evaluate the null hypothesis of optimization.

The t-test used to evaluate the null hypothesis produces three factors of importance, namely the t-statistic, t-critical statistic and a probability value (P). These are shown in Table 4.4.2.1. Theoretically the t-statistics in the t-test measures the size of the difference in the mean values of the distributions relative to the variation in the sample. If the t-statistic is larger than the t-critical statistic the null hypothesis is

rejected. The t-statistic goes hand in hand with the probability value and if P is less than 0.05 ( $\alpha$ ) it is also good reason to reject the null hypothesis.

The CA and CA + LV t-test results shows that the t-statistic is much larger than the t-critical statistic, 3.56 compared to 1.96. For both these procedures a very low P value of 0.0004 was obtained, which strengthens the large t-statistic result that confidently rejects the null hypothesis. This means that for CA and CA + LV it can be confidently said that the dose was optimized during this project.

The CA + PTCA + 1 Stent, PPM and Ablation t-test results show a t-statistic that is larger than t-critical, but the difference is not as clear as in the case of CA and CA + LV. For these three procedures the t-statistic was 2, 2.08 and 2.33 and the t-critical statistic was 1.97, 1.97 and 1.98 respectively. The P values for these procedures were 0.047, 0.039 and 0.022 which is in agreement with the t-statistic in rejecting the null hypothesis. This means that for CA + PTCA + 1 Stent, PPM and radiofrequency ablation it can be confidently said that the dose was optimized during this project.

However, for biventricular PPM the t-test results show a t-statistic of 0.89 which is smaller than the t-critical statistic of 2.02. The P value for biventricular PPM was calculated as 0.38 which is higher than  $\alpha$ . This means that the t-test cannot confidently reject the null hypothesis for biventricular PPM. Despite the 19% DRL improvement noted for this procedure, the statistics of the results do not support this. The high SD in the biventricular PPM cases and the low amount of procedures performed during Q4 2013 may have influenced the t-test results. The average SD for biventricular PPM was 155 Gy.cm<sup>2</sup> with only 26 procedures recorded in Q4 2013.

The optimization of radiation dose and improvement in DRLs may be attributed to various factors. This program, to the involved theatres, managed to increase their

awareness and understanding of the DAP measurement and the dose delivered to a patient. For many of these theatres this was their first involvement in DRL calculation or dose optimization. Baseline values, theatre averages and group averages allowed theatres to compare their improvement with neighbouring hospitals that often housed similar x-ray equipment.

The availability of a local DRL metric, indicating a dose level that should not routinely be exceeded, helped the responsible medical physicists to identify, investigate and optimize imaging techniques. The newsletters that were sent out explicitly mentioned the hospitals' names, which resulted in a degree of competition between hospitals.

The DRL data helped the responsible physicist to engage with theaters that had the same equipment, but higher doses, to determine where optimization could happen. The improvements made to the incident management system included the definition, quantification or grading and guided management of incidents. This enforced the same radiation protection principles and helped to achieve responsible radiation usage.

During the SAAPMB conference of 2007, Gray said, *“typically if the radiologist in fluoroscopy doesn't like the way an image looks, he tells the service engineer to fix this. What does the service engineer do if the radiologist doesn't like the image? He turns up the exposure rate.”* (77)

My experience during this work may include in the above statement that cardiologists and vascular surgeons are not much different. Unfortunately, they have much less knowledge and comprehension of their actions when adjusting radiographic techniques. The scenario discussed at theatres 12 and 18 demonstrated this. When

DRLs are correctly applied and form part of the dose management in interventional fluoroscopy, scenarios like the above can be more easily observed and addressed.

This DRL system made outlier identification possible and theatres continually exceeding the DRL could be investigated and a lack of improvement could be questioned. The availability of a locally derived DRL and comparisons with achievements of other centers aided administrators to motivate, where needed, for the upgrading of equipment. During the course of this work some imaging equipment, like theater 22, was replaced or upgraded with newer technology, which surely had a positive impact on the DRL.

During SAAPMB 2007 Dr Joel Gray from the United States, when closing the preliminary session, challenged the South African medical physicists by saying, "*First and foremost, we have to look at optimized image quality and dose. Again my challenge to you, let's look at the 50% DRL as the goal for our own departments.*"

(77)

This concept of using the 50% DRL level for comparisons and optimization worked very well in the private hospital group where this study was performed. Dose levels were optimized and DRLs were not high in comparison to international levels. We can confidently say, in response to the challenge set by Dr Gray, that for CA and PTCA, the South African private sector DRLs appear to be even lower than those published in the United States by Miller *et al.* (64) in 2012.

## CHAPTER 6 CONCLUSION

The NCRP report 160 (46) mentions that radiation is widely used in medicine for diagnostic, interventional and for functional imaging as well as for radiotherapy. The situation regarding X-ray imaging in South Africa is no different, as these techniques offer great benefit to patients. Today, many doctors from various disciplines are relying on digital X-ray imaging to perform surgeries and clinical procedures on patients. Unfortunately, use of digital X-ray technologies carries risk and can lead to overexposure of patients if applied incorrectly.(1)

Ionizing radiation has the potential to cause stochastic and deterministic adverse radiation effects like radiation induced cancer and erythema, dermal atrophy and even tissue necrosis. (2, 7) Interventional theatres, and specifically interventional cardiology theatres, have a high usage of interventional X-ray machines.

Unfortunately, the training of these specialist doctors does not include adequate radiographic technique training or radiation safety training. Interventional procedures are becoming increasingly more complex in many specialities, as the types and uses of catheters become more advanced.(5, 16)

In South Africa, since 2007, it has been regulated that DAP meters must be installed in fixed fluoroscopy units. In 2015, these regulations were updated and now require that patient DAP readings are optimized by a medical physicist. Currently there are very limited publications in South Africa, referring to DRLs and no full publications addressing interventional cardiology. These factors, as listed above, emphasized the urgent need for this work.

This study covered 20415 interventional procedures segregated into 24 procedure categories performed at 27 interventional theatres during the period of June 2012 to December 2013 across South Africa. Six procedures with high incidence and relevance were further evaluated. These represented 15473 cases, or 76% of the total procedure amount.

The distribution of DAP values for complex interventions, e.g., CA+ PTCA + 1 Stent and biventricular PPM, displayed a high variation in the data as shown by the large standard deviation and inter-quartile ranges. The diagnostic procedures and less complex interventions, like CA, CA+LV, PPM and radiofrequency ablation, showed smaller deviations and inter-quartile ranges.

EVAR procedures consistently accounted for the highest mean DAP values during this work. Closer investigation of the practise and the radiological technique used showed excessive usage of high pulse rate fluorography and high dose fluoroscopy. The vascular surgeons could allow technique and fluorography frame rate adjustment down to 7.5 fps and low dose fluoroscopy. Mean EVAR doses for theatres were greatly reduced by applying these simple technique changes.

Theatre number 12 consistently, and with a large margin, exceeded the group mean value for many procedure types. Closer investigation into the radiographic technique showed that the cardiologists only use fluorography to perform their cases because the fluoroscopy image quality was deemed insufficient. The radiographers were unsuccessful in their efforts in having this poor technique changed. The medical physicist gave firm instructions detailing that fluorography should not be used routinely for screening purposes, but only when essential and when image recording is required. The correction of this poor technique and some additional optimization

training resulted in theatre 12's mean CA dose reducing by 44% and CA +LV by 34%.

The research question introduced in this work has two parts. Firstly, *“Are radiation doses used in South African private healthcare interventional laboratories high compared to those published internationally”* and secondly, *“will establishing dose reference levels optimize the doses used?”*

The mean and SD of DRLs from many countries worldwide was calculated.

Comparisons with the DRLs from this work and these international mean values plus one SD were made. To address the first part of the null hypothesis, it can confidently be concluded that South African private healthcare doses are not high in comparison with international levels.

The second part of the null hypothesis was whether DRLs would optimize radiation doses used. The t-test results showed that it can confidently be concluded that for all procedures, except for Biventricular PPM, DRLs optimized doses within the six quarters of this review. The uncertainty highlighted by the t-test done on Biventricular PPM was likely caused by the wide variation in the doses and the low case numbers recorded for the last quarter.

These reductions in DRLs, that the t-tests have confirmed to be statistically significant in all but one study, translate to a 13 % improvement for CA, 18 % for CA+LV, 9 % for CA + PTCA + 1 Stent, 13 % for PPM, 19 % for biventricular PPM and 45 % for Radiofrequency Ablation.

One challenge for small centres and also for uncommon procedures, like Biventricular PPM, is to get enough cases in a dataset to provide a statistically useful

result. This is especially difficult when there is a wide SD and IQR in a distribution. Calculating a DRL for procedures with a low frequency remains challenging.

Considering the importance of DRLs, I feel the expression “miners’ canary” may have relevance to theatres with low numbers or poor statistics for complex interventions. The metaphor originates from the times before technology when there were no real-time gas meters in coal or other mines. These miners of old used to carry caged canaries while at work. The theory behind this was, if there were dangerous levels of methane or carbon monoxide in the mine, the canary would die. This “miners’ canary” would be an early warning system. The expression “miners’ canary” or “canary in a coal mine” has been used widely as a metaphor to indicate possible triggers or identifiers before obvious symptoms appear. (129-131) The evaluation of local DRLs of diagnostic procedures and simple interventions, which have higher case numbers and neater distributions, may be the “miners’ canary”. Should the simpler diagnostic procedures indicate elevated DAP levels compared to the DRL, then this may indicate bigger problems for interventions, because the same dose optimization and reduction principles apply for diagnostic procedures and complex cases.

The reductions seen were not without challenges and it remains difficult to engage the specialist doctors who control the dose. Attempts to provide free training and advice were largely unsuccessful because specialists working in their private capacity do not have time or possibly interest to attend such sessions. The lack of training of these doctors is a big problem and the examples of theatres 12 and 18 detailed in this work are testament to it.

A possible solution to this could be compulsory training programmes that insist that all specialists using X-rays should have radiation protection training when specializing. This would mean approaching all academic hospitals or even the Health Professions Council of South Africa, to make it part of the curriculum.

Limited comparisons between private and public sector doses have recently become possible because of the abstract published by Makosa & Conradie (81) from one South African public healthcare institution in 2015. They published initial levels of 153 Gy.cm<sup>2</sup> for CA and 43 Gy.cm<sup>2</sup> for PPM. These levels appear high compared to the private sector doses proposed in this work of 57 Gy.cm<sup>2</sup> and 36 Gy.cm<sup>2</sup>.

However, this is a very small sample and no real conclusion can be made by this comparison.

For the majority of the 27 interventional theatres that participated, this was their first attempt at dose optimization and for many their first interaction with a medical physicist. The realization of dose management and the training of professionals that work in these theaters resulted in an awareness shift. Radiation dose quantifies, like the DAP reading, that were previously unnoticed in some theatres, have become an important dimension to assess high quality interventional techniques.

We attribute the improvement seen to various factors, including increased awareness created, changes in imaging techniques, new and upgraded imaging equipment and the improvement of incident management. This is an on-going study within the private hospital group where this work was done. Following this initial work, Annexure 8.4 highlights some current advances and improvements to this DRL program.

It is generally accepted that the benefit of interventional radiology, compared to the risks of complicated invasive surgery, greatly outweighs the deterministic and stochastic radiation risks inherent in the modality. We must, without question, avoid any deterministic effects of radiation and also restrict stochastic risks, and DRLs can highlight problem areas.

This research aimed to establish if DRLs in the South African private healthcare interventional theatres are high compared to international levels and whether DRLs will optimize the doses used. The results indicate that South African doses are not high in comparison and that establishing an on-going DRL program to monitor and compare radiation doses used in intervention, will assist with dose optimization leading to lower patient radiation doses.

I propose, based on the number of cases recorded and the national spread of the participating private hospital group in South Africa, that these DRLs could be considered guidance to interventionists in the private sector, attempting to optimize their techniques using DRLs for their patients.

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## **CHAPTER 8 ANNEXURE**

### **8.1 Ethical Considerations**

The information used in this dissertation already exists and was retrospectively analysed as an audit. The recording of the information used is a legislated requirement from the Department of Health, Directorate Radiation Control. (DoH DRC). The latest equipment licensing requirements entail that the user records and optimizes DAP readings for patients in fixed fluoroscopy procedures. (17) The proposed data was anonymised at the source and no patient names or numbers exist in the data set.

The data includes the hospital name, procedure name, date of screening and the DAP reading of procedures done in a private hospital group's facilities from June 2012 until December 2013. All hospital names were removed from the dataset. Any incidents/problems noticed in the data that could potentially be harmful to the patient were recorded by the hospital concerned on their Incident Management System (IMS) and handled separately according to the applicable internal policies and legislation pertaining to such incidents.

The University of Cape Town, Human Research Ethics Committee, granted approval for this study under the reference HREC REF: 254/2014. Additionally, the private healthcare institution, Research Operations committee, granted ethical approval for this research with reference UNIV-2015-0032.

## 8.2 Procedure Descriptions

Table 8.2.1: Procedure name and descriptions used for the first 14 procedures included in the study. Procedure descriptions were mostly sourced from web based sources used for patient educational purposes.

Name	Also known as	Procedure Description
Coronary Angiography	CA (Coronary Angiogram) / Cardiac Catheterization	Cardiac Catheterization/Coronary Angiography is an invasive test to find out whether or not there are any narrowing or blockages in the coronary arteries and how well the heart is pumping. A vessel in the right leg is punctured with a needle and then a small plastic tube, called a catheter is passed up to the heart arteries under x-ray guidance. A special x-ray dye is then injected which allows pictures of the heart to be seen and information is recorded permanently.(132)
Cerebral Angiography	Cerebral Angiogram	Cerebral angiography is a test that enables doctors to see a map of the blood vessels in the brain and the neck by using a contrast agent (special dye) and fluoroscopy. It also helps to show how blood flows between the different parts of the circulation. Typically a catheter is inserted into a large artery (such as the femoral artery) and threaded through the circulatory system to the carotid artery, where a contrast agent is injected. A series of radiographs is taken as the contrast agent spreads through the brain's arterial system, then a second series as it reaches the venous system. (133)
Renal Angiography	Renal Angiogram / Renal Arteriography	This is a study of the blood vessels of the kidneys. It is done by inserting a catheter and using a contrast medium and fluoroscopic imaging.

CA + Angioplasty (Balloon)	Percutaneous Coronary Intervention (PCI) / Percutaneous Transluminal Coronary Angioplasty (PTCA) / Percutaneous Coronary Angioplasty (PCA)	Angioplasty is the technique of widening blocked / narrow cardiac arteries with a balloon. This is a way of opening up blocked / narrowed coronary arteries and increasing the blood flow to the area of heart muscle they supply. The initial part of the procedure is the same as for coronary angiography, except the catheter has a balloon tip. Once the catheter is in place a thin wire, called a guide wire, it is threaded through the catheter towards the narrowed section of the artery. Over this the doctor will advance the angioplasty catheter that has a balloon at the tip. This may be repeated a few times until the artery is opened adequately.
CA + Angioplasty (+ Stent)	CA + Coronary Angioplasty (+Stent) / PTCA & Stent/ Stent	A stent is a small, metal coil that helps keep a “ballooned” artery open. It acts as a support on the inside of the artery.  Stents are mounted on a balloon catheter. The process for implanting a stent is the same as a coronary angioplasty except when the balloon is inflated, the stent is imbedded to the inside of the artery, while the balloon is deflated and removed. Thus leaving the stent behind. Include procedures where multiple stents are used.
Ablation (RF)	Catheter Ablation - Radio Frequency / Cardiac RF ablation / Radio Frequency ablation	Catheter ablation is an invasive procedure used to remove a faulty electrical pathway from the hearts of those who are prone to developing cardiac arrhythmias. Catheter ablation uses a series of thin, flexible wires (catheters) that are inserted through an artery or a vein (usually in the groin or neck) and guided to the heart. The catheter tip is an electrode which then delivers a low-voltage, high-frequency current that destroys the heart tissue responsible for the arrhythmia. This procedure will also include some electrophysiological studies.

Ablation (RF + Robotic)	All Catheter ablation using a Robotic device  Pulmonary Ablation - RF + Robotic	Pulmonary vein ablation is a treatment for atrial fibrillation. It is standard catheter ablation done on one or more of the four pulmonary veins using a robotic device. There are very few hospitals that do this procedure.
EPS	Electro Physiology Study	An electrophysiology study (EPS) is a minimally invasive procedure which tests the electrical conduction system of the heart to assess the electrical activity and conduction pathways of the heart. The study is to investigate the cause, location of origin, and best treatment for various abnormal heart rhythms.
CA + LV function	CA + LV function Left Ventriculography	Left Cardiac Ventriculography is a medical imaging test used to determine a patient's cardiac function in the left ventricle. Cardiac ventriculography involves injecting contrast media into the heart's ventricle to measure the volume of blood pumped. The 3 major measurements obtained by cardiac ventriculography are: Ejection Fraction, Stroke Volume & Cardiac Output. This procedure will also include a Coronary Angiogram, but Right Ventriculography (RV) should not be included in this study.(134)
CA + LV + Angioplasty (Balloon)		This is a Cardiac Left Ventriculography study with an Angioplasty. During this procedure the patient's cardiac function will be evaluated where after the blocked arteries will be opened with a catheter with a balloon tip.
CA + LV + Angioplasty (+ Stent)		This study is identical to a LV function study with an Angioplasty, but this includes a Stent placing. Includes procedures where multiple stents are used.
Pacemaker (Permanent)	Pacemaker/ PPM	A pacemaker (or artificial pacemaker, so as not to be confused with the heart's natural pacemaker) is a medical device that uses electrical impulses, delivered by electrodes contacting the heart muscles, to regulate the beating of the heart. (135)

Pacemaker (Bi Vent)	Biventricular Pacemaker / CRT (Cardiac Resynchronization Therapy)	A biventricular pacemaker is a type of pacemaker that can pace both the septal and lateral walls of the left ventricle. By pacing both sides of the left ventricle, the pacemaker can resynchronize a heart whose opposing walls do not contract in synchrony, which occurs in approximately 25-50 % of heart failure patients.(135)
TAVI	Valve placement / Trans catheter Aortic Valve Implantation	A catheter with a balloon tip is inserted through the groin into the heart. Once the end of the balloon is in the aortic valve, the balloon is inflated to stretch open the narrowed aortic valve. This is called valvuloplasty. A new valve is then carefully compressed and mounted onto another balloon delivery catheter, using a specially designed device, and threaded into the aortic valve. The balloon is used to expand the new valve. The new valve is designed to settle itself in place firmly.

Table 8.2.2: Procedure name and descriptions used for the additional 10 procedures included in the study in January 2013. Procedure descriptions were mostly sourced from web based sources used for patient educational purposes.

Name	Also known as	Procedure Description
Cerebral Angiography + Interventions	Neuro-Angiogram + Interventions	This is a Cerebral/Neuro-Angiogram followed by any interventions e.g. Embolism / Stents / Coiling procedure/Gluing
Peripheral Angiography	Peripheral Angiogram / Peripheral Arteriogram	A peripheral angiogram is a test that uses X-rays to help your doctor find narrowed or blocked areas in one or more of the arteries that supply blood to your legs.
Peripheral Interventions		During peripheral interventions doctors open blocked or narrowed blood vessels caused by peripheral arterial disease or

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		other conditions.
CA + EPS	Coronary angiogram + Electro Physiology Study	This is an Electro Physiology study preceded with a coronary angiogram.
CA + EPS + Ablation	CA + EPS + Catheter ablations	This is an Electro Physiology study preceded with a coronary angiogram and follow by a cardiac ablation. Cardiac ablation is a procedure that is used to destroy small areas in your heart that may be causing your heart rhythm problems.
CA + LV + Angioplasty + 2 Stent	CA+ LV + Angioplasty (+ Stent) LV + Stent	This study is identical to a LV function study with an Angioplasty, but this includes a Stent placing.
CA + LV + Angioplasty + 3 Stent	CA+ LV + Angioplasty (+ Stent) LV + Stent	This study is identical to a LV function study with an Angioplasty, but this includes a Stent placing.
EVAR	Endovascular Aneurysm Repair / Endovascular Aortic Repair	Endovascular aneurysm repair (EVAR) is an alternative to open surgery for the treatment of abdominal aortic aneurysms (AAAs).
Permcaths	Central Venous Catheters (Permanent) Permanent Catheters	This is when a catheter is permanently (or for a long term) inserted into the patient's arteries.
Paediatric Diagnostic heart cath	Paediatric Diagnostic left & right heart	This study only includes paediatric cases (all other cases are excluded). During cardiac catheterization, doctors thread long, flexible tubes, called catheters, up through a child's large blood

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catheters

vessels and into the heart. These catheters allow them to measure pressures and draw blood samples. They use these measurements to determine how blood is flowing to different parts of your child's body. Sometimes an angiogram is included in this study to see important anatomic details of the child's heart.

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### 8.3 Dose Optimization Newsletters



31/01/2013

Dear Interventional Radiology and Cardiology Team

**Radiation Dose Optimization Program: 1<sup>st</sup> Quarter Feedback 2013**

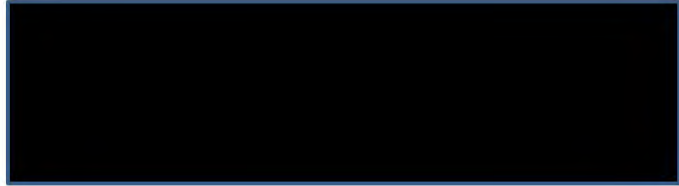
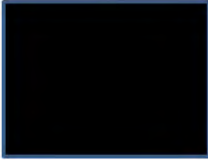
January 2013 marks 6 months since we started the attempt at radiation dose optimization in [redacted] Cathlabs. The 14 procedures initially selected have since been expanded to 24 and our Diagnostic Reference levels were determined in 2012. The project has been presented at SA Heart (SunCity), SAAPMB and various ISCAP events around South Africa. Recently on the 27 Sept 2012 the US Food & Drug Association (FDA) published an attempt at dose optimization in the United States of America (USA) covering approximately 300 catheterization facilities. They report radiation doses significantly higher than in Europe and conclude that doses are not optimized in US practice. This article [is available here](#) for your reference and it is encouraging that South Africa is not that far behind.

The table on the next page indicate the average [redacted] DRL for 2012 as well as some International Atomic Energy Agency (IAEA) references and other published sources. The data indicate that the [redacted] average is still generally higher than the reference levels, but it seem to be decreasing and this is great news. Congratulations to the hospitals that were able to reduce their doses in the past quarter, these hospitals are highlighted in green on the graphs attached.

Please visit the [IAEA's](#) website where you will find free training material & techniques to reduce dose to patients & staff when doing interventional procedures. Remember DRLs are intended to be a reasonable indication of dose for average-sized patients, and to provide guidance on what is achievable with current good practice rather than optimum performance. Thank you again for everyone's contribution to this project and if you have any concerns, please contact your hospital medical physicist.

Kind regards,  
[redacted] Medical Physics CoE

Figure 8.3.1: The first page of the motivation and feedback letter issued in January 2013.



22/07/2013

Dear Interventional Radiology and Cardiology team

**Radiation Dose Optimization Program: 2<sup>nd</sup> Quarter Feedback 2013**

June marked a year since the dose optimization program has been implemented. This year has been extremely exciting, informative but also an eye opener to the radiation doses patients receive as part of interventional procedures. Our aim of this program is to optimize doses for the South African patient population as much as possible and to establish our own DRLs (Diagnostic Reference Levels). Remember DRLs are intended to be a reasonable indication of dose for average-sized patients, and to provide guidance on what is achievable with current good practice rather than optimum performance.

We have seen great success at most hospitals regarding optimization and would specially like to congratulate the following labs that were able to optimize/reduce their radiation dose with 15% (or more) within this year: [REDACTED] (Lab 2), [REDACTED] (Labs 1 & 2), [REDACTED], [REDACTED] (EP lab), [REDACTED] and [REDACTED] (Lab 2). The table on page two gives a summary of the percentage optimization for [REDACTED] labs. By optimizing radiation doses delivered to patients in interventional units we decrease the probability of deterministic risks (skin burns) to the patients, and also reduce dose delivered to medical professionals working in the lab.

We reported on the optimization data quarterly, with June to September 2012 being the baselines, the second quarter was from, October to December 2012 and the third quarter from January to March 2013. The graph on the 3<sup>rd</sup> page is a summary of the year's results as a normalized average of all 24 procedures. Additionally, find attached some procedure specific results where international DRLs are used for comparison.

We are excited to announce that this entire dose optimization program has been developed into a web based system. This system will enable daily data capturing (or at one's own pace), eliminate various possible human errors and will display immediate notes if for example a data entry has exceeded the procedure specific average dose by more than 50%. If you want to volunteer to test the 'beta' version of the program, please contact your physicist. Thank you again for your valuable contribution to the program. If you have any questions or concerns, please contact your hospital medical physicist.

Kind regards,

[REDACTED] Medical Physics CoE

Figure 8.3.2: The first page of the motivation and feedback letter issued in July 2013.

## 8.4 Optimization Program Advances

This dissertation details the aim, important decisions, and results of the first six quarters of the DRL and dose optimization project done in a South African private hospital group.

This first year and a half of implementation was a learning experience for everyone involved, which includes the medical physicists. The teething lessons and problems that were mentioned included (lack of) doctor participation, procedure descriptions determination and some system problems. Considering the legislation in South Africa (17), the longevity of a project like this required the development of an online system to assist with data collection and also improve accuracy.

The online system was developed by the private medical physics division in conjunction with programmers employed by the private hospital institution. This program was tested by a few beta hospitals in September 2013, after which it went live in January 2014. Since then the system is running with minimal supervision.

Theatres are able to access their data and don't need to wait for quarterly feedback letters to assess their improvement or lack thereof. Figures 8.4.1-2 shows screenshots of the online system on the intranet of the private hospital group. Figure 8.4.3 shows screenshots of messages displayed by the online system if high doses are entered.

During the SAAPMB congress of 2015 further reference level advice and possible DRLs were presented. (136) This updated work originated from the lessons learnt in the first six quarters described herein.



Figure 8.4.1: A screenshot of the online dose optimization system.

**Patient Dose Optimisation**

Capture Month:  
 Month:

Hospital Info:  
 Hospital:

Lab:

Procedure Info:  
 Procedure Date:

Procedure Performed:

Exposure Time (min):

Patient Weight (Kg):

Patient Height (cm):

Dap Reading:

DAP Unit:

|  |

- (Select)
- Coronary Angiography
- Cerebral Angiography
- Cerebral Angiography + Interventions
- Renal Angiography
- Peripheral Angiography
- Peripheral Interventions
- CA + Angioplasty/PTCA
- CA + Angioplasty/PTCA + Single Stent
- Ablation (RF)
- Ablation (RF + Robotic)
- EPS
- CA + EPS

Figure 8.3.2: The data input page of the online dose optimization system.

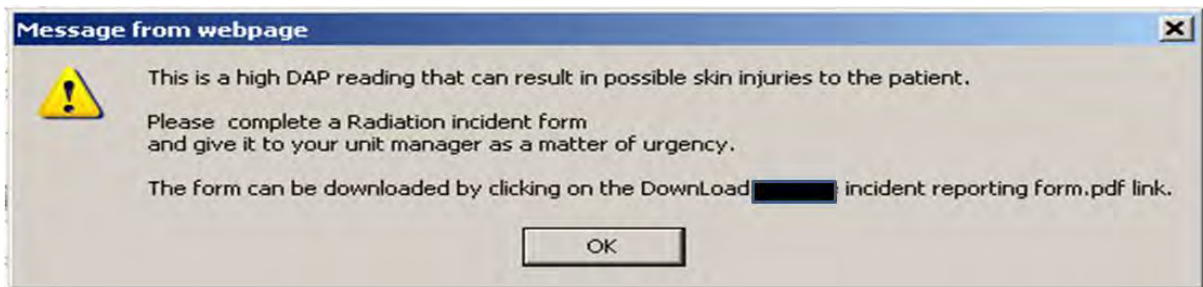
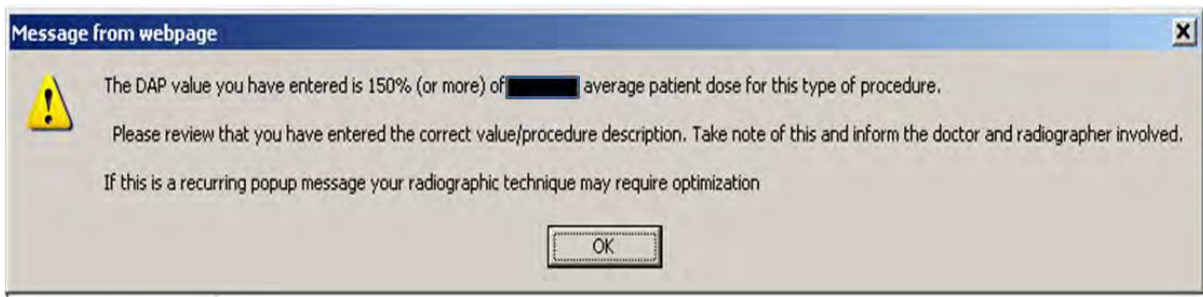


Figure 8.3.3: Screenshots of the pop-up warning messages produced by the online system should a high value be entered.