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Proposed DRLs for Mammography in Switzerland

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Abstract

Objectives:

The aim of this study is to propose Diagnostic Reference Levels (DRLs) values for mammography in Switzerland.

Methods:

For the data collection, a survey was conducted among a sufficient number of centres, including 5 University hospitals, several cantonal hospitals, and large private clinics, covering all linguistic regions of Switzerland to be representative of the clinical practice. The data gathered contained the mean glandular dose (MGD), the compressed breast thickness (CBT), the mammography model and the examination parameters for each acquisition. The data collected was sorted into the following categories: 2D or digital breast tomosynthesis (DBT) examination, craniocaudal (CC) or mediolateral oblique (MLO) projection, and 8 categories of compressed breast thickness (CBT) ranging from 20mm to 100mm in 10mm intervals.

<u>Results:</u>

A total of 24762 acquisitions were gathered in 31 centres on 36 mammography units from six manufacturers. The analysis showed that the data reflects the practice in Switzerland. The results revealed that the MGD is larger for DBT than for 2D acquisitions for the same CBT. From 20-30mm to 90-100mm of CBT, the 75th percentile of the MGD values obtained increased from 0.81mGy to 2.55mGy for 2D CC acquisitions, from 0.83mGy to 2.96mGy for 2D MLO

acquisitions, from 1.22mGy to 3.66mGy for DBT CC acquisitions and from 1.33mGy to 4.04mGy for DBT MLO acquisitions.

Conclusion:

The results of the survey allow us to propose Swiss DRLs for mammography according to the examination type (2D/DBT), projection (CC/MLO) and CBT. The proposed values are very satisfactory in comparison with other studies.

Critical Relevance Statement

The first establishment of DRLs for mammography in Switzerland is the starting point for an optimized practice.

Key Points

- 1. Establishing the first DRLs for mammography in Switzerland
- 2. The mammography DRL values obtained in Switzerland are representative of the practice and compare well to those established in other countries
- 3. The availability of DRLs for mammography will help for the optimization of these procedures

Key Words

Diagnostic Reference Levels, Mammography, Radiation protection, Switzerland

List of Abbreviations

- **CBT: Compresses Breast Thickness**
- CC: Craniocaudal
- CR: Computed Radiography
- DBT: Digital Breast Tomosynthesis
- DMS: Dose Management System
- DR: Digital Radiography
- DRL: Diagnostic Reference Level

 FFDM: Full Field Digital Mammography

MGD: Mean Glandular Dose

MLO: Mediolateral Oblique

Introduction

Breast cancer is a highly prevalent cancer among women. In 2020, it was the most common cancer worldwide but was only the fifth on the list of the most common causes of cancer deaths; however, early diagnostics and screening via mammography examinations help to reduce cancer mortality [1].

In Switzerland, breast cancer affects around 6,300 women each year, and is still the leading cause of death from cancer with approximately 1,400 women dying from it annually [2].

Mammography is the basic examination of the breasts that can detect changes in breast tissue, diagnose and manage patients having breast disorders. On top of the diagnostic mammography performed for a suspicious breast tissue modification or appearance, a screening programme in Switzerland provides women over 50 the opportunity to have a mammography every two years.

In 2018, screening mammography represented 0.97% of the total X-ray examinations in Switzerland corresponding to 0.3% of the dose contribution of the X-ray modalities. For what concerns diagnostic mammography examinations, these represented 1.74% of the X-ray examinations, corresponding to 0.6% of the total dose of the X-ray modalities [3].

Breast tissue is known to be a highly radiosensitive organ [4-6]. Thus, it is crucial to optimize its exposure during diagnostic and screening mammograms. Unlike other diagnostic examinations, for mammography, the European Commission has established acceptable and achievable values of mean glandular dose (MGD) per compressed breast thickness (CBT) ranging from 21 to 90 mm for screening examinations [7]. The concept of diagnostic reference levels (DRLs) is recognized internationally as an important tool to optimize patient's exposure [8]. DRLs are used as benchmark values that help ensure the optimization of radiation dose in medical imaging procedures. By setting these reference levels, healthcare providers can consistently monitor and manage the radiation exposure delivered to patients during mammography. Comparing MGD values with national or international DRLs is a good way to get an overview of the practice. DRLs should be viewed not as limits, but as dose indicators, establishing a DRL will lead to optimisation when necessary. According to ICRP 135 [8] a DRL value is defined as the 75th percentile of the distribution of the median values of the participating institutes obtained by the survey.

In Switzerland, even though DRLs exists for almost all modalities [9], no DRL has yet been established for mammography.

The aim of the present study is to establish national DRLs for mammography examinations in Switzerland, based on a survey performed in 31 Swiss centres, including university hospitals, canton hospitals and private clinics, to obtain a representative overview of the practices. Data was collected for 2D full field digital mammography (FFDM which will be referred to as 2D in this article for simplicity) and digital breast tomosynthesis (DBT) mammography examinations with a wide variety of parameters, such as different CBT, projections, and digital mammography devices.

Materials and methods

Data collection

The data collection was organized by contacting the medical physicists from the 5 University hospitals in Switzerland and those working in the different canton hospitals and large private clinics to cover all regions of Switzerland. In total, we collected data from 31 of the 206 (15%) institutes in Switzerland, and from 36 of the 252 (14%) digital mammography units in the country. The data was collected for 2D and DBT mammography examinations including both diagnostic and screening mammograms.

Several parameters influence the MGD of a mammogram. Different MGD are delivered for large CBTs [13-14], for DBT examinations compared to 2D exams, and for MLO (mediolateral-oblique) compared to CC (craniocaudal) projection. Therefore, the questionnaire specifically requested 20 acquisitions per each 10 mm thickness interval and per projection, for 2D and DBT examinations.

The breast is composed of glandular and adipose tissues, each in different proportions specific to each individual which change with the breast thickness and age of the patient. The proportion of glandular/adipose tissue determines the breast density, which influences the MGD [12]. Glandularity is not easily accessible or exportable via the dose management system (DMS) and was not evaluated in this study. Therefore, some studies conducted on DRLs in mammography present results according to age categories in addition to other categories (2D/DBT), projections, CBT, etc. [13].

Questionnaire

A questionnaire for data collection was sent to the medical physicists in early October 2021. Data was collected until March 2022.

The first part of the questionnaire consisted of general questions about the mammography unit (manufacturer and model of the system) and the centre (name of the institute, contact details of the correspondent). One questionnaire per unit had to be provided. Instructions for completing the questionnaire accurately were also provided.

Requirements for the data were the following:

- only data from female patients were gathered.
- It was aimed at a minimum of 20 acquisitions per each category of compressed breast thickness interval (8 categories, from 20 to 100 millimetres thickness in 10mm intervals), projection (CC and MLO) and for 2D and DBT separately.
- If 20 acquisitions were not feasible, respondents were requested to provide as much data as possible for each category, and the units were still included in the analysis.
- the provided data had to be the most recent consecutive data.

The second part of the questionnaire was the one that had to be filled in with the following data for each acquisition provided:

- Acquisition Type (2D/DBT)
 - Projection (CC/MLO)
 - Compressed Breast Thickness (CBT)
 - Mean Glandular Dose (MGD) displayed by the mammography unit.

Data analysis

The analysis was performed with data arranged according to the following categories:

- 2D/DBT
- Projections CC/MLO
- CBT

Regarding the dosimetric quantity to use for establishing DRLs, the ICRP 135 [8] provides three different possibilities: Entrance-surface air kerma ($K_{a,e}$), Incident air kerma ($K_{a,i}$), and MGD, but suggests to use MGD, as also proposed in other publications [10,12]. For this reason, and because MGD represents the mean absorbed dose in the breast glandular tissue and is related to the radiological risk of induced cancer, we decided to use MGD as dosimetric quantity in this study. This value, determined by mammography system, can be subject to a range of uncertainty, dependent on the system and the dose model used for calculation [15-18]

The proposed DRLs were defined for single acquisitions. DRLs for single acquisitions directly allow evaluating how well the acquisition parameters are optimized. DRLs for whole examinations would depend also on the number and type of acquisitions which is rather a question of justification than optimization.

Data was received from 31 centres, for a total of 36 devices. The total number of acquisitions collected was 24762, 14925 for 2D mammography (Table 1) and 9'837 for DBT exams (Table 2), for both CC and MLO projections and for each 10 mm CBT interval. The minimum of 20 requested acquisitions could not be reached for the extreme categories of CBT for each mammography unit.

<u>Results</u>

Our first step was to evaluate whether the mammography units for which we collected the data were representative of the models used in Switzerland. In total, we analyzed data from 14% of the mammography units installed in Switzerland. These mammography units represent more than 87% of the most commonly used models, which are the models for which 10 or more units are installed in Switzerland. For DBT examinations, we collected data from 4 out of the 7 models that can perform these examinations.

According to ICRP 135 [8], a DRL value is defined as the 75th percentile of the distribution of the medians of the datasets obtained through a survey. For each unit, the median MGD was therefore calculated for 2D/DBT exams, for CC/MLO projections and for each CBT interval. The distributions of the median MGD are depicted as boxplots in Figure 1 for 2D mammograms and Figure 2 for DBT mammograms.

The 75th percentile of the MGD values obtained for 2D and CBT between 20mm and 100mm are comprised between 0.81mGy – 2.55mGy for CC and between 0.83mGy - 2.96mGy for MLO. For DBT, the values are comprised between 1.22mGy – 3.66mGy for CC and 1.33mGy – 4.04mGy for MLO. MGD are higher for DBT than for 2D, and for MLO than for CC.

The substantial difference in MGD values between the lowest and highest CBT intervals shows the importance of analyzing the data for different CBT values. The steady increase of the 75th percentile MGD values from CBT interval to CBT interval indicates that the collected dataset was sufficiently large and that the 10 mm CBT intervals were large enough to calculate robust CBT-specific DRL values.

The advantage of considering the medians of each mammography unit is that they all have the same statistical weight in the final results. It is important that each unit has an equivalent weight compared to the others, otherwise the units that have provided more data will have a greater impact on the final results, which will no longer be representative of all the units. We therefore consider this method as the appropriate one to propose DRLs.

DRLs proposal

The 75th percentile of the distribution of the median MGD is presented in Table 3 for 2D/DBT, for each projection (CC/MLO) and for each CBT interval. These results represent the proposed DRLs for Switzerland.

Discussion

Thanks to this survey, we have been able to propose a DRL value for 2D mammography acquisitions and DBT, for each 10-millimetre interval of CBT ranging from 20 to 100 millimeters, and for both CC and MLO projections. These results were computed by calculating the 75th percentile of the medians from all the mammography units that provided data. These results are proposed to become the first DRLs for mammography in Switzerland.

The comparison between our results with those from other countries should be made very carefully since different methodologies have been used, some made their DRLs using patient survey, and some using PMMA phantoms [10-11, 13, 19-22]. Therefore, we have chosen to compare our results with those obtained by countries that applied the same methodology (i.e., patient survey). When considering our study alongside others, it's crucial to acknowledge divergent statistical approaches in establishing Dose Reference Levels (DRLs). Unlike our use of the 75th percentile and median, some studies opt for the 95th percentile and mean values. These methodological distinctions may contribute to observed differences in reported dose levels, warranting careful interpretation when comparing findings across studies.

Some countries have, like us, chosen to separate their results by CBT intervals as shown in Table 4. The New South Wales study shows results for separated CBT intervals of 10 mm likewise our results. Their range is larger, from 20 mm to 110 mm, while we have considered a maximum CBT of 100 mm [21]. The New South Wales study consider different detector technologies, but, since we only have DR systems, we have compared our results only with the DR ones. The values they obtained for DR vary from 0.97 to 2.63 mGy generally higher than ours for all CBT intervals and projections, except for 70 to 80 mm CBT interval for MLO projection, and for 90 to 100 mm interval for MLO projection, where our values are slightly higher. For what concerns the results obtained for the CR technology, they are much higher than our results.

The Scotland study also presents results for DR and CR, for several larger CBT intervals of 20 mm and include values of CBT below 30 mm and above 80 mm (for DR only) [19]. Their DR results vary from 0.73 to 2.81 mGy, generally higher than ours, except for the CBTs below 30 for which their value is lower than our 20 mm to 30 mm result. For CR, their values vary from 1.59 to 3.22 and are higher than ours.

In the study from Turkey, the results presented are separated in the same CBT and projection categories than our study, adding two age categories for patients aged 40-49 and 50-64 [13]. The calculated values vary from 2.00 to 2.60 mGy for patients aged 40-49 CC projection, and from 2.40 to 50 mGy for MLO projection. Results vary from 2.10 to 3.00 mGy for CC projection and from 2.30 to 4.00 for MLO projection for patients aged 50-64. The results from this study are generally higher than ours, except for the 90 to 100 mm CBTS for CC projection for both age categories, where our values are higher. An interesting point is the introduction of the age as a category for establishing DRLs. As mentioned earlier, breast density (glandularity) has an influence on the delivered dose and it is indeed changing with age. Nevertheless, the key parameter remains glandularity rather than age. Unfortunately, glandularity is not an easily accessible parameter nor exportable via the DMS.

Other countries have set their DRLs values for an average CBT value, some separating for CC and MLO projections. To compare our work with their results, we use the values obtained by pooling the data for 2D and DBT separately, for CC and MLO projections, for a mean CBT value. The results for our data when proceeding this way are presented in Table 5, in comparison with two other studies with similar methodologies.

The DRLs proposed by IRSN in 2021 [11] were 1.7 mGy for 2D for a mean CBT of 56 mm, and 2.3 mGy for DBT for a mean CBT of 57 mm. In our study, DRLs for 2D mammograms are 1.29 mGy for an average CBT of 56 mm and 1.42 mGy for an average CBT of 58 mm for CC and MLO respectively. DRLs for DBT examinations are 1.79mGy for an average CBT of 54mm and 1.91 mGy for an average CBT of 56 mm for CC and MLO respectively. The values of the French report and ours, when obtained using the same method, are quite similar. Slightly higher values have been obtained in Ghana for the 2D, with a DRL set at 75th percentile with a MGD of 2 mGy for a CBT 60±5 mm [22].

In conclusion, our results are in good agreement with those of other countries when using a similar method.

Limitations

The findings of this study have to be seen in light of some limitations. First, during data collection, some institutes, mainly small institutes, were unable to participate, as they did not have a DMS. Gathering data without DMS can be very time-consuming and tedious. This greatly limited the number of institutes willing to participate in our study, and therefore the amount of data.

We encountered a second limitation during data collection. We had asked the participating institutes to send us, if possible, 20 data per category of 10-millimeter intervals of CBT. However, cases for extreme CBTs (very small or very large) are less common than intermediate values. Many centers were therefore unable to collect the 20 data requested for these categories.

We also had to neglect the influence of age and/or breast glandularity, which can have a strong impact on the dose delivered. To consider the influence of these factors, we should have added different categories of glandularity, which would have enormously increased the amount of data expected for each center. Moreover, glandularity is a not easily accessible data via the DMS, and collecting this information would therefore have been very time-consuming.

Furthermore, while our study relies on the MGD determined by the mammography system, it is important to acknowledge the inherent uncertainty associated with this quantity. The accuracy of the recorded MGD values is contingent upon factors such as the mammography system in use and the dose model employed for calculation. These inherent uncertainties highlight a limitation in the precise quantification of MGD levels and emphasize the need for cautious interpretation of the results in the context of these potential variations.

Finally, variations in dose levels across different manufacturers' equipment could contribute to observed differences in our study. Notably, the data, particularly in digital breast tomosynthesis (DBT), is predominantly based on one supplier. Caution should be exercised when extrapolating findings to other manufacturers. Recognizing this variability in equipment is essential for a nuanced interpretation of our results.

Conclusion

To propose DRL values for mammography examinations performed in Switzerland we followed the recommendations established by the International Commission on Radiological Protection [8]. To this end, we performed a survey allowing us to collect data from 36 mammography units installed all over the country. The data, categorized into different categories such as examination type (2D or DBT), projection (CC or MLO) and 8 different CBT categories of 10mm width, ranging from 20mm to 100mm was analysed. The data is representative of the practice in Switzerland since the most frequently installed models are represented. The MGD is larger for a DBT acquisition than for 2D, it increases as the CBT increases and has higher values for MLO than CC. Finally, diagnostic reference levels (DRLs) were proposed as a function of the examination type (2D/3D), projection (CC/MLO) and CBT. The proposed values compare well to those obtained in the literature.

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Table 1 - Number of acquisitions provided for each mammography device model, for 2D, for both CC/MLO projections, and 10 mm CBT intervals.

Madala	N	CC							MLO								Total	
Models	units	20-30 mm	30-40 mm	40-50 mm	50-60 mm	60-70 mm	70-80 mm	80-90 mm	90-100 mm	20-30 mm	30-40 mm	40-50 mm	50-60 mm	60-70 mm	70-80 mm	80-90 mm	90-100 mm	TOTA
Hologic - Selenia Dimensions	6	69	188	335	450	446	198	54	24	117	241	357	459	542	315	114	40	394
Hologic - 3Dimensions	2	25	74	82	143	127	60	39	6	29	69	80	127	131	81	52	18	114
Siemens - Mammomat Inspiration	11	204	203	203	203	205	184	187	106	136	136	137	137	124	117	111	101	249
Siemens - Mammomat Revelation	3	121	296	582	841	753	386	102	26	11	30	108	252	253	158	41	20	398
IMS Giotto - Giotto Class	5	100	100	100	100	100	100	97	31	100	100	100	100	100	100	100	77	150
General Electric - Senographe Essential	2	18	26	39	64	58	33	15	6	21	23	38	55	60	41	25	4	526
Philips - Microdose Mammography L30	1	11	8	12	13	8	9	9	7	9	12	8	7	12	11	11	13	160
Philips - Microdose L50	1	8	8	12	9	10	11	8	7	12	12	8	11	10	9	12	13	160
Philips - Mammo Diagnost DR		11	8	13	8	10	10	8	1	9	12	7	12	10	10	12	0	141
Fujifilm - Amulet FDR	3	40	41	57	56	65	55	54	15	44	71	70	87	85	63	43	21	867
Total	35	607	952	1435	1887	1782	1046	573	229	488	706	913	1247	1327	905	521	307	1492

Table 2 - Number of acquisitions provided for each mammography device model, for DBT, for both CC/MLO projections, and 10 mm CBT intervals.

Models	N					Ċ							MI	_0				Total
modelo	units	20-30 mm	30-40 mm	40-50 mm	50-60 mm	60-70 mm	70-80 mm	80-90 mm	90-100 mm	20-30 mm	30-40 mm	40-50 mm	50-60 mm	60-70 mm	70-80 mm	80-90 mm	90-100 mm	
Hologic - Selenia Dimensions	4	44	72	103	117	109	62	7	1	62	89	111	146	136	100	64	22	1245
Hologic - 3Dimensions	2	104	378	699	1030	648	251	64	13	116	377	610	907	741	374	123	51	6486
Siemens - Mammomat Inspiration	5	21	25	39	40	40	30	19	1	61	76	81	96	100	82	66	34	811
Siemens - Mammomat Revelation	1	i								20	20	20	20	20	20	20	20	160
IMS Giotto - Giotto Class	4	77	80	80	80	80	80	67	37	64	77	80	80	80	80	59	34	1135
Total	16	246	555	921	1267	877	423	157	52	323	639	902	1249	1077	656	332	161	9837

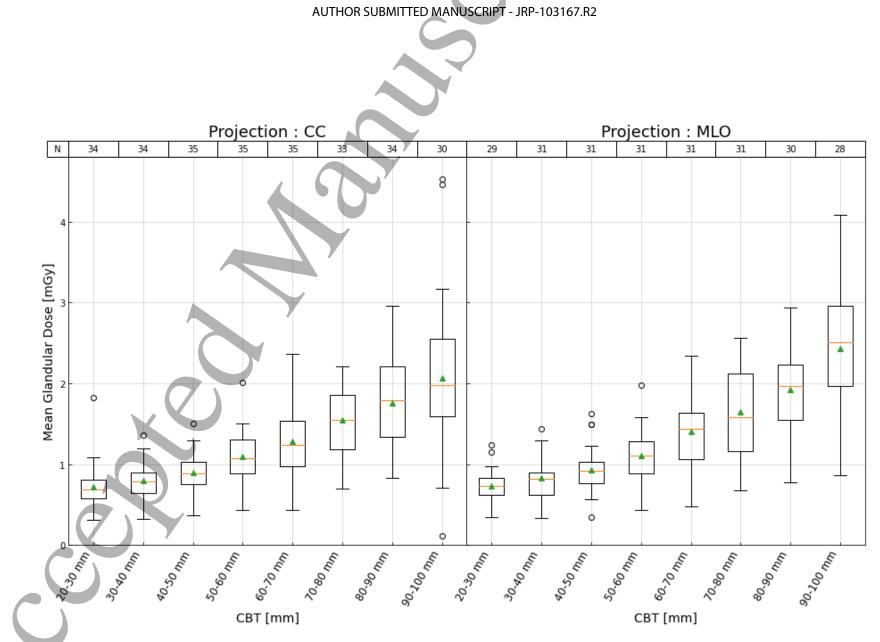
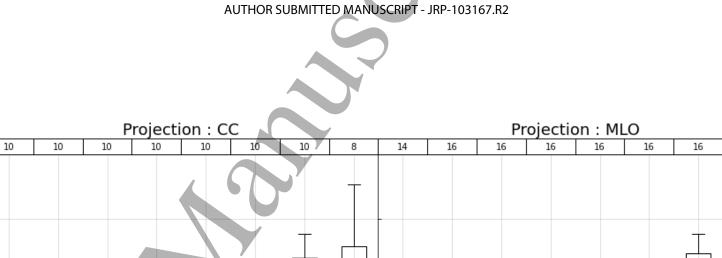


Figure 1 - Boxplots of median values of MGD of all mammography units, for 2D acquisitions, CC and MLO projections, for all CBT intervals.



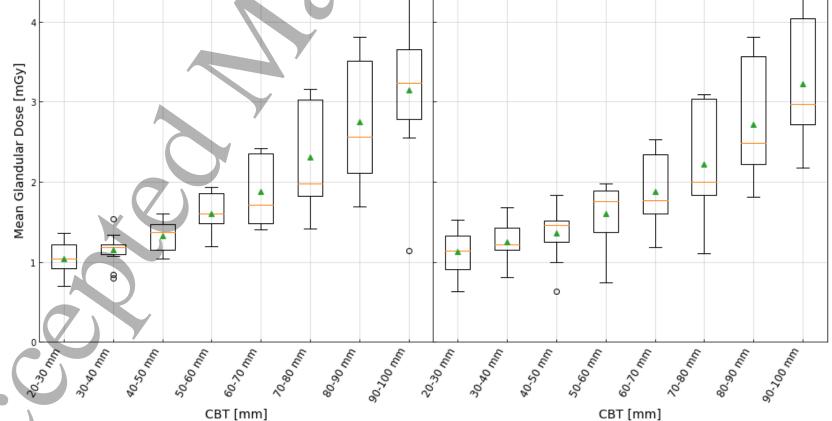


Figure 2 - Boxplots of median values of MGD of all mammography units, for DBT acquisitions, CC and MLO projections, for all CBT intervals.

Ν

Table 3 - Proposed DRLs values for mammography examinations in Switzerland (MGD per acquisition).

CC												М	LO				
СВТ	[mm]	20- 30	30- 40	40- 50	50- 60	60- 70	70- 80	80- 90	90- 100	20- 30	30- 40	40- 50	50- 60	60- 70	70- 80	80- 90	90- 100
2D	MGD	0.81	0.90	1.03	1.31	1.54	1.86	2.21	2.55	0.83	0.90	1.03	1.28	1.64	2.12	2.23	2.96
DBT	[mGy]	1.22	1.22	1.47	1.85	2.35	3.03	3.51	3.66	1.33	1.42	1.52	1.89	2.34	3.04	3.57	4.04

Table 4 - Results for 2D/DBT and CC/MLO projections and for 10 mm CBT intervals (MGD per acquisition), in comparison with other studies. "Std" is the standard deviation of the set of data.

						0	CBT [n	nm]			
			20-30	30-40	40-50	50-60	60-70	70-80	80-90	90-100	100-110
		2D - CC	0.81	0.9	1.03	1.31	1.54	1.86	2.21	2.55	
	Our ctudy	DBT - CC	1.22	1.22	1.47	1.85	2.35	3.03	3.51	3.66	
	Our study	2D - MLO	0.83	0.9	1.03	1.28	1.64	2.12	2.23	2.96	
		DBT - MLO	1.33	1.42	1.52	1.89	2.34	3.04	3.57	4.04	
	New South Wales	2D	0.97	1.12	1.3	1.65	2.35	2.08	2.34	2.63	3.31
MGD [mGy]	Scotland	2D	0.73	1.	08	1.51	2.	16	2.81		
	Turkey (Age 40-49)	2D - CC	2	2.2	2.2	2.3	2.6	2.6	2.3	2.5	
	Turkey (Age 40-49)	2D - MLO	3	2.4	2.5	2.6	2.8	3.2	3.3	3.5	
	Turkey (Age 50-64)	2D - CC	2.6	2.1	2.2	2	2.5	2.6	3	2.2	
	Turkey (Age 50-64)	2D - MLO	3.1	2.4	2.5	2.3	2.5	2.9	3.3	4	



Table 5 - Results for all data pooled for 2D/DBT and CC/MLO projections and for a mean CBT value (MGD per
acquisition), in comparison with other studies. "Std" is the standard deviation of the set of data.

MC	BD [mGy]		2D		DBT	
	CC	MLO	CC	MLO		
	Median	1.10	1.18	1.61	1.75	
	75th perc.	1.29	1.42	1.79	1.91	
Our study	95th perc.	1.55	1.84	1.94	2.10	
	std	0.26	0.34	0.22	0.31	
	Mean CBT [mm]	56	58	54	56	
France	Median		1.70		2.30	
France	Mean CBT [mm]		56		57	
	75th perc.		2.00			
Ghana	95th perc.		4.20			
	Mean CBT [mm]		60			