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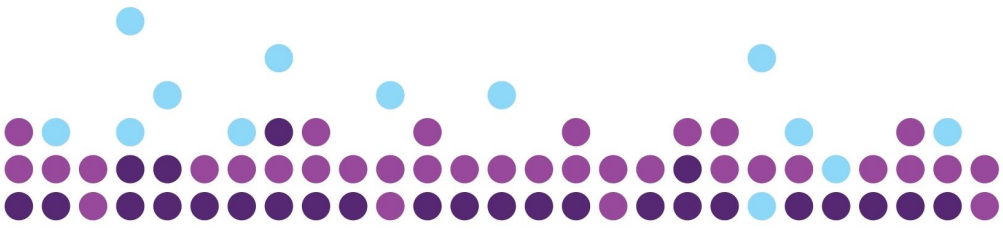

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D9.143 - Acceptance and quality control protocols for skin dose calculating software solutions in interventional cardiology

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Abstract

In interventional cardiology (IC), patients may be exposed to high doses to the skin resulting in tissue reactions (skin burns) following single or multiple procedures. As the number and complexity of IC procedures have been steadily growing, online and offline software has been developed to estimate the maximum skin dose (MSD) to the patient during (or after) IC procedures. However, the capabilities and accuracy of such skin dose calculation (SDC) software to estimate MSD and 2D dose distributions markedly differ among vendors. In addition, there is currently no protocols for testing such systems prior to release into clinical use or on regular basis.

Acceptance and quality control (QC) testing protocols for the accuracy of SDC software in interventional cardiology were developed. The Acceptance protocol is composed of 13 fundamental irradiation set-ups and 3 clinical procedures, intended to represent more realistic conditions. The QC protocol is based upon the Acceptance protocol and is made of 8 fundamental irradiation set-ups. Measurements were performed following the Acceptance protocol on a GE Innova IGS 540, a Philips Allura Xper, a Siemens Artis Zee biplane and a Canon Infinix CF-i biplane. Calibrated solid-state dosimeters (multimeters), gafchromic films and thermoluminescent dosimeters were used for the measurements. Skin dose estimates were performed with 10 SDC software products in total: CareMonitor, Dose Tracking System, DOSE by Qaelum, DoseMap, em.dose, OpenSkin, Radiation Dose Monitor, DoseWatch Skin Dose Map (two versions) and SkinCare. At least 4 software products and up to 8 were used in combinations with a specific angiographic unit, depending on compatibility.

The MSDs estimated by most SDC software products was within ±40% of the measurements during the fundamental irradiations and the clinical procedures. However, about half of the software products could not provide MSD estimates for lateral irradiations because a flat phantom was used. Among the remaining software products, accuracy of the MSD estimate for lateral irradiations was quite variable and could be very poor. Most SDC software produced maps representing acceptably the dimensions, the shape and the relative position of the MSD region. Some software, however, could miss the MSD region when situated at the thin intersection of multiple fields. The dimensions and shape of the MSD region were inaccurate for all SDC software on the Philips system because wedge filters were used, while most SDC software assumes square irradiation fields

SDC software solutions can produce acceptable results and may include fine technical details of the procedure as calculation input; however, the determination of the patient body contour and position remains challenging. This can dramatically degrade the software accuracy particularly for lateral irradiations and irradiations that are not centred on the patient's back.

I. Foreword

This document describes Acceptance and quality control (QC) testing protocols for the accuracy of skin dose calculation (SDC) software in interventional cardiology. The protocols were developed and tested in the frame of the VERIDIC project (Validation and Estimation of Radiation skIn Dose in Interventional Cardiology). This project has received funding from the Euratom research and training program 2014-2018 under grant agreement No 662287. Detailed information about the protocol development and other project results are available in the project deliverables (https://concert-h2020.eu/en/Publications), on the project ResearchGate page (https://www.researchgate.net/project/VERIDIC-Validation-and-Estimation-of-Radiation-skIn-Dose-in-Interventional-Cardiology) or by contacting the authors.

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II. Acronyms and abbreviations

BSF: Backscatter factor
CAU: Caudal
CRA: Cranial
FOV: Field Of View
$K_{a,r}$: Air kerma at the reference point
LAO: Left Anterior Oblique
LLAT: Left Lateral
MSD: Maximum Skin Dose
PA: Posterior Anterior
PACS: Picture Archiving and Communication System
P_{KA}: Air Kerma-Area Product
PMMA: Polymethyl methacrylate
QC: Quality Control
RA: Rando Alderson
RAO: Right Anterior Oblique
RDSR: Radiation Dose Structured Report
RLAT: Right Lateral
SDC: Skin Dose Calculation
SID: Source to Image detector Distance
TLD: Thermoluminescent dosimeter

III. Introduction

In interventional cardiology (IC), patients may be exposed to high doses to the skin resulting in tissue reactions (skin burns) following single or multiple procedures. As the number and complexity of IC procedures have been steadily growing, patient-specific dose calculation in IC has become a research priority over the years. To address this issue, online and offline software has been developed to estimate the maximum skin dose (MSD) to the patient during (or after) IC procedures. However, the capabilities and accuracy of such skin dose calculation (SDC) software to estimate MSD and 2D dose distributions markedly differ among vendors; and the reporting of the MSD estimate and the related accuracy in the Radiation Dose Structured Report (RDSR) is neither systematic nor harmonised. In addition, there is currently no acceptance testing and quality control (QC) protocols of such systems.

Hence, the VERIDIC (Validation and Estimation of Radiation skIn Dose in Interventional Cardiology) project aimed to contribute to the harmonisation of the RDSRs and the validation of SDC software solution in IC in order to optimize patient dose. Three work packages were created to achieve those objectives. The present document reports the results of the second work package dedicated to developing acceptance and quality control (QC) protocols for SDC software solutions.

The Acceptance and QC protocols are described in sections IV and V, respectively; acceptability criteria are also proposed. Furthermore, measurements following the protocols were performed on different angiographic systems combined with various software tools. The software performances are presented in section VI. Finally, to extent the comparison of those tools to clinical cases, they were used to estimate skin dose for a large data base of clinical examinations as reported in section VII.

IV. Acceptance protocol

A. Introduction

The Acceptance protocol is composed of 13 fundamental irradiation set-ups and 3 clinical procedures, intended to represent more realistic conditions. In practice, the Acceptance protocol should be performed post installation and prior to releasing the skin dose calculation (SDC) software product into clinical use.

The fundamental irradiation set-ups were chosen to verify that key parameters which can significantly affect the maximum skin dose (MSD), were appropriately taken into account by SDC software. Effect of the air kerma at the reference point ($K_{a,r}$) calibration, the attenuation of the table and the mattress, different patient thicknesses and overlapping x-ray projections are investigated individually. Only limited values of those key parameters are tested in the proposed fundamental set-ups. There are many other parameters affecting the skin dose (such as the field size or the use of in-field collimation, for example) which cannot be tested in the limited time available to the medical physicists in clinical practice. It is therefore proposed to perform the clinical procedure set-ups in addition to fundamental set ups, to estimate the accuracy of the skin dose calculations.

The protocol was developed to be performed within a limited timeframe. The fundamental irradiation set-ups can be performed in one afternoon, while two or three additional hours can be necessary to perform the clinical procedures. The exact duration obviously depends on the characteristics of the selected dosimeter and the physicist's experience in manipulating the angiographic system. In addition, restricted/limited access to desired technical settings may prove very challenging when testing the system. Some creativity and flexibility are therefore necessary when performing the protocol.

B. Material

1. Dosimeters

Calibrated thermoluminescent dosimeters (TLD), radiochromic films or QC dosimeter[1] can be used, depending on availability.

If the dosimeters are calibrated in air kerma, the measured doses need to be converted to kerma into tissue or water so that a comparison with the skin dose calculations of SDC software can be made as per equations 1 and 2.

Many QC dosimeters do not respond to backscatter radiation. In this case, the displayed doses should be corrected for backscatter contribution following equation 2.

Detectors covering a large surface area, such as gafchromic films or multiple point dosimeters such as TLDs, are necessary for some tests to make sure the MSD is measured. A single dosimeter such as QC dosimeter can be used for all other irradiation configurations.

2. Phantoms

Polymethyl methacrylate (PMMA) plates (6 plates of 5 cm thickness, 30 x 30 cm² surface) are required in order to build phantoms of various thickness (10, 15, 20, 25 and 30 cm). This represents paediatric or small adult patients up to a large adult patient.

[1] The term QC dosimeter in this document refers to all kind of multipurpose devices, sometimes called x-ray detectors or multimeters, used for measurements of QC parameters.

An adult Rando Alderson (RA) phantom, which represents a patient weighing about 75 kg, is used to investigate the effect of beam angulations on a realistic patient representation; alternatively a 25 cm thick PMMA slab phantom which also represents a patient weighing about 75 kg can be used.

3. Lead and copper sheets

Sufficient lead or copper sheets are put in front of the image detector in order to generate the desired tube voltage (kVp) for the $K_{a,r}$ measurements performed in the automatic brightness/exposure control mode. If the tube voltage settings can be selected in engineer mode, lead and copper sheets are not necessary.

4. Dose report

The dose report or the radiation dose structured report (RDSRs) should also be transferable if the skin dose calculations are to be performed using post-procedure software tools which are not connected to the modality or the picture archiving and communication system (PACS).

C. Experimental setup

The protocol is composed of 13 fundamental irradiation set-ups and 3 clinical procedures. The detailed set-up of the fundamental irradiations is described in section *Fundamental irradiation set-ups.* The detailed set-up of the clinical procedures is described in section *Clinical procedures.* Ideally, the 3 clinical procedures should be selected from high-dose procedures performed on an angiographic system comparable to the one equipped with SDC software, and shortened following the method described in Annex 2: clinical procedures Alternatively, the 3 clinical procedures as used in the project can be used (Table 2). Procedure parameters must be adapted to fit the specific system features (e.g., the fields of view (FOV) listed in the table might not be available; the closest values should be selected). The x-ray system should have passed routine QC tests in accordance with national requirements. If fundamental irradiation set-ups 1 to 4 have already been performed as part of the system routine QC tests, they do not need to be repeated.

1. Fundamental irradiation set-ups

a) Registration of a new examination/patient

- A **standard adult patient** is registered (> 18 years, height and weight as reported in Table 1 or as recommended by the manufacturer), supine. This step should not be overlooked because some SDC solutions rely on this data for the phantom selection in the dose calculation module.
- The **most commonly used clinical cardiology protocol** is selected.

b) Dosimeters and phantom set-up

- When **mattress** is indicated in the protocol table, only one single mattress is to be used, unless more are usually used in clinical practice
- A **slab PMMA phantom**, a **RA anthropomorphic phantom** or **no phantom at all** is used, as described per event in Table 1.
- The dosimeter is always positioned in the primary beam **at the patient entrance reference point** (usually isocentre minus 15 cm), except for event 14, as depicted in Figure 1 to Figure 3. To assure the repeatability of the measurements, the position of the dosimeters should be kept identical for all measurements. This is particularly important for solid-state QC dosimeters since they will significantly affect the exposure settings in the automatic brightness/exposure control regime.

- When a phantom is used, the dosimeter is positioned **on the mattress under the phantom at the patient entrance reference point** (usually isocentre minus 15 cm). A jig might be necessary to support the phantom and place the dosimeter underneath, care should be taken not to introduce any material in the primary beam which could cause scatter (Figure 1 and Figure 2). For example, the phantom can be placed on a jig made of an extruded polystyrene foam panel with a recession to host the dosimeter(s).
- If necessary, a radiopaque object, such as a radiopaque ruler, is used prior to the irradiation event in order to determine the overlapping position of the radiation fields and to accurately position the dosimeters.
- For lateral irradiations (event 13, LLAT or RLAT), the dosimeter is positioned **on the side of the phantom** (Figure 3).
- The **estimated doses from each fundamental irradiation event** as described in Table 1 should be available individually to allow comparison with the measured doses. Depending on the system capabilities, it might be necessary to register each radiation event as an individual examination to obtain the dose estimate.

c) Geometry of the irradiations (Figure 1 to Figure 3)

- The **table height** is such that the top of the mattress is positioned at the patient entrance reference point (usually isocentre minus 15 cm) as in Figure 1 and Figure 2; for purely lateral irradiations (event 13, left lateral (LLAT) or right lateral (RLAT)), the table height can be freely selected (Figure 3).
- The x-ray source to image detector distance (**SID**) is 100 cm.
- The **x-ray tube angulation (projection)** is reported for each event in Table 1. The 10 first irradiations events are performed in posterior anterior (PA) configuration only. Irradiation event 13 is purely lateral; irradiation events 11 and 12 are a combination of up to three projections (PA, lateral oblique (LAO) and cranial (CRA)). The terminology used for the beam angulation is described in Annex 1: Beam angulation terminology.

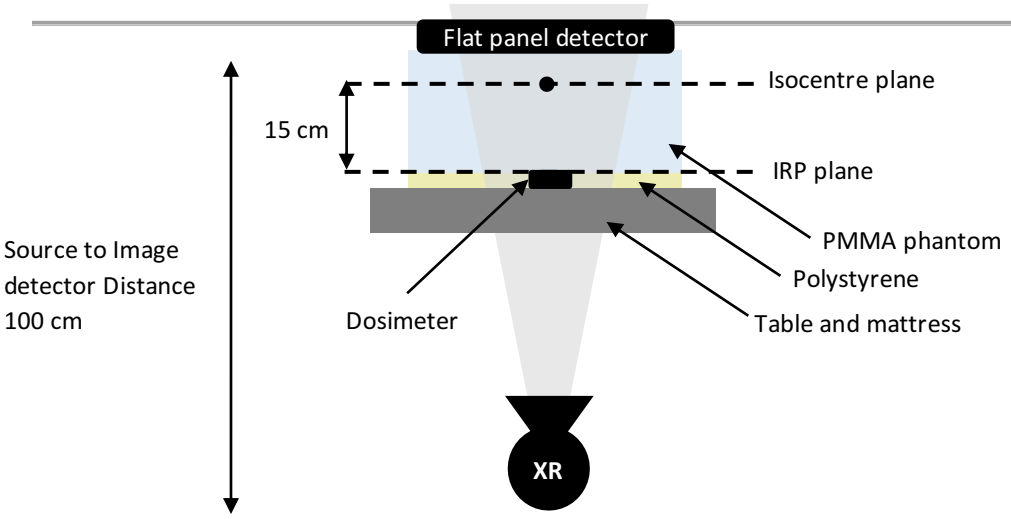

Figure 1: Experimental set-up: posterior anterior irradiation

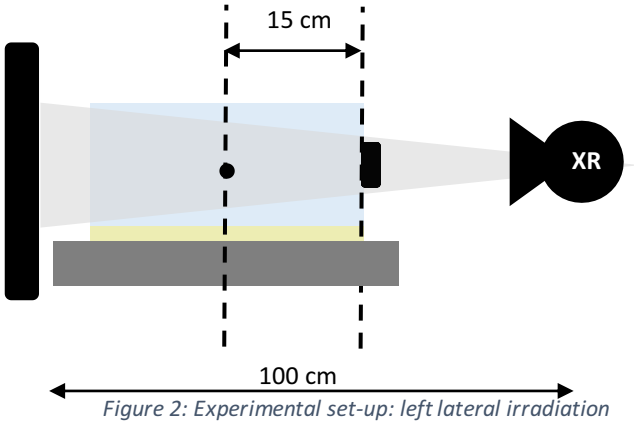

Figure 2: Experimental set-up: left lateral irradiation

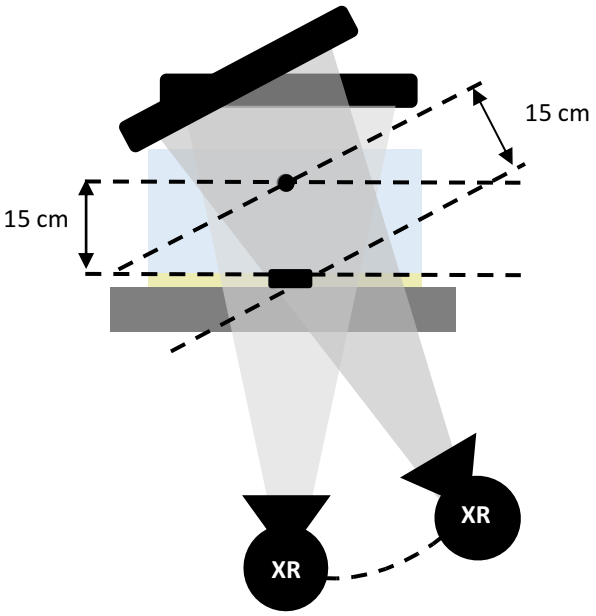

Figure 3: Experimental set-up: combined posterior anterior and left oblique irradiations

d) Selection of the examination settings

- One **FOV** of 20 cm or as close as possible is used. No in-field collimation is used.
- The **tube voltage and the added filtration** are set automatically by the system. The 4 first irradiation events (without phantom) should be performed at low and high tube voltage (kVp). Lead sheets or objects (such as a thyroid protection or an apron) can be placed ideally on the flat panel detector or anywhere between the dosimeter and the flat panel detector to obtain the desired tube potential. An x-ray transparent jig can be used for that purpose.
- The irradiations are all performed in **acquisition mode** with highest image frame rate (15 or 30 fps) if necessary to obtain a tube output sufficiently high.
- The **dose levels to be reached** at the dosimeter depends on its detection capacities and the SDC software product to be tested. One should strive to obtain doses sufficiently high to allow adequate dosimeter reading and skin dose calculation. For example, few mGy or less are sufficient for thermoluminescent dosimeters and QC dosimeters and might be sufficient for MSD calculations, and at least a few hundreds mGy are necessary for gafchromic films.
- One should attempt to obtain $K_{a,r}$ of the same order of magnitude for each tube angulation when more than one angulation is used in an event (event 11 and 12). In addition, the width of the field overlapping region should always be bigger than 1 cm^2 and it should cover the dosimeter. The FOV can be increased if necessary.

Table 1: Acceptance protocol: Fundamental irradiation set-ups

Irradiation event	Purpose of measurement	Configuration	Projections	Tube potential	Age (years)	Height (cm)	Weight (kg)
1[1,2]	$K_{a,r}$ calibration	Free in air	PA	low (~80 kVp)	NA	NA	NA
2[1,2]	$K_{a,r}$ calibration	Free in air	PA	high (~120 kVp)	NA	NA	NA
3[1]	Effect of the mattress and table attenuation	On mattress + table	PA	low (~80 kVp)	NA	NA	NA
4[1]	Effect of the mattress and table attenuation	On mattress + table	PA	high (~120 kVp)	NA	NA	NA
5[3]	Effect of the phantom scatter	Phantom 20 cm + mattress + table	PA	Automated selection	Adult	170	70
6[3]	Effect of the phantom scatter; thicker patient	Phantom 25 cm + mattress + table	PA	Automated selection	Adult	170	80
7[3]	Effect of the phantom scatter; thicker patient	Phantom 30 cm + mattress + table	PA	Automated selection	Adult	170	90
8[3]	Effect of the phantom scatter; thinner patient	Phantom 15 cm + mattress + table	PA	Automated selection	Adult	160	55
9[3]	Effect of the phantom scatter; thinner patient	Phantom 10 cm + mattress + table	PA	Automated selection	Adult / Paediatric	140	45
10[3]	Effect of the phantom scatter; thinner patient	RA Phantom + mattress + table	PA	Automated selection	Adult	170	75
11[4]	Effect of field overlap	RA Phantom + mattress + table	PA + LAO 20	Automated selection	Adult	170	75
12[4]	Effect of field overlap	RA Phantom + mattress + table	PA + LAO 20 + PA CRAN 15	Automated selection	Adult	170	75
13[4]	Effect of lateral irradiations	RA Phantom + mattress + table	LLAT or RLAT	Automated selection	Adult	170	75

[1] No MSD is calculated nor measured for those irradiation events
[2] Lateral irradiations (LAO or RAO90) can be used instead of PA if the phantom is positioned perpendicularly to the table.
[3] Except for dosimeters which do not respond to backscatter, such as most QC dosimeters
[4] A 25 cm thick PMMA slab phantom can be used if no RA phantom is available.

2. Clinical procedures

a) Registration of a new examination/patient

- A **standard adult patient** is registered (> 18 years; 170 cm and 75 kg or as recommended by the manufacturer), supine. That step should not be overlooked because some SDC solutions rely on those data for the dose calculations.
- The most commonly used clinical **cardiology protocol** is selected.

b) Dosimeters and phantom set-up

- Only **one single mattress** is placed on the table, unless more are usually used in clinical practice.
- A **Rando Alderson anthropomorphic phantom** or a **25 cm thick PMMA slab phantom** which represent a patient weighing about 75 kg is positioned on the table
- The dosimeter is positioned **on the mattress under the phantom**. A jig might be necessary to support the phantom and place the dosimeter underneath. Care should be taken not to introduce any material in the primary beam which could cause scatter radiation. For example, the phantom can be placed on a jig made of an extruded polystyrene foam panel with a recession to host the dosimeter(s) as depicted in Figure 1.
- If necessary, a radiopaque object, such as a radiopaque ruler, is used prior to the irradiation event in order to determine the overlapping position of the radiation fields and to accurately position the dosimeters.
- The **measured, cumulative doses from each individual procedure** as described in Table 2 should be available to allow comparison with the calculated doses.
- The **dose should be cumulated over a complete procedure**. Some active dosimeters might only provide the dose per event. In that case, the measured dose is summed up over all procedure events.

c) Geometry and selection of the examination settings

- The **table height, the SID and the angular position of the tube** (primary and secondary angles) are set individually for each event of the procedure as per Table 2.
- The **FOV** for each event of the procedure is reported in Table 2
- The **tube voltage and the added filtration** are set automatically by the system
- The irradiations are all performed in **acquisition mode** with highest image frame rate (15 or 30 fps) if necessary to obtain a tube output sufficiently high.
- The **desired $K_{a,r}$ contribution** of each event is given in Table 2 so that a cumulative $K_{a,r}$ of 1000 mGy is reached for each procedure. This value can be adapted to the dosimeters and SDC software capabilities.

Table 2: Clinical procedure set-ups and typical cumulative $K_{a,r}$. A RA anthropomorphic phantom or a 25 cm thick PMMA slab phantom, which represent a 170 cm tall patient weighing 75 kg.

Event	Primary Angle (+ = LAO)	Secondary Angle (+ = CRA)	Collimated Field Area (m^2)	Field of view (cm)	SID (cm)	Table Height[1] (cm)	Cumulative $K_{a,r}$ (Gy)
Procedure 1							
1	**-30**	**-10**	0.03	24	104	16	0.15
2	**-30**	**-5**	0.02	20	101	16	0.1
3	**-25**	**-5**	0.02	20	104	16	0.12
4	**30**	**-15**	0.03	24	100	15	0.37
5	**30**	**-5**	0.02	20	104	16	0.1
6	**35**	**-15**	0.03	24	104	16	0.16
Procedure 2							
1	**30**	**5**	0.02	20	94	10	0.2
2	**25**	**-5**	0.03	24	97	10	0.18
3	**30**	**0**	0.03	24	104	10	0.16
4	**-10**	**5**	0.01	14	102	10	0.12
5	**20**	**0**	0.01	14	103	10	0.12
6	**-30**	**30**	0.04	28	105	10	0.22
Procedure 3							
1	**20**	**10**	0.02	20	112.1	5	0.41
2	**50**	**0**	0.02	20	119.6	5	0.2
3	**-30**	**15**	0.02	20	112.1	5	0.11
4	**25**	**35**	0.02	20	120	5	0.11
5	**30**	**20**	0.02	20	116	5	0.1
6	**50**	**10**	0.02	20	116.3	5	0.07

[1] distance from table top to isocentre

D. Deviation of the measured MSD

The deviation between the calculated and the measured MSD value *can* be calculated following equation 1 for dosimeters measuring the contribution from backscattered radiations and calibrated in air, and following equation 2 for dosimeters shielded against backscattered radiations.

$$Dev(\%) = \left(\frac{D_{calc}}{D_{meas} \times f_{air,water}} - 1\right) \times 100\ \% \quad (1)$$

$$Dev(\%) = \left(\frac{D_{calc}}{D_{meas} \times f_{air,water} \times BSF_{water}} - 1\right) \times 100\ \% \quad (2)$$

Where D_{calc} is the MSD calculated by the SDC software, D_{meas} is the dose measured by the dosimeter, *BSF* is the backscatter factor and $f_{air,water}$ is the ratio of mass energy-absorption coefficient water-to-air. The BSF value for water for various square field sizes can be calculated according to ICRU-74 (ICRU 2006), the IAEA TRS-457 (Alm-Carlsson et al 2007) or Benmakhlouf et al. (2011, 2013), who provide the most complete range to date. A dedicated Excel sheet implementing Benmakhlouf et al (2011, 2013) approach for BSF calculations is available upon request; the BSF value is calculated based on the beam energy (characterised by kV and HVL), the field dimensions and the phantom material and thickness. The $f_{air,water}$ value can be calculated using the mass-energy absorption coefficients available on the website of the National Institute of Standards and Technology, for example. Ideally the value for $f_{air,water}$ should be determined and used for each individual irradiation. In practice, a single value of 1.06 can be used without significantly affecting (maximum 5%) the measurement uncertainty (Benmakhlouf et al. 2011).

E. Acceptability criteria

The calculated MSD values should **not differ more than 40% from the measured values** (ie, *|Dev(%)|< 40%)* for any of the fundamental irradiations events from 5 to 12[2] and any of the clinical procedures. Deviation of more than (±) 40% can be acceptable for very specific cases. These include the following:

- Deviation of more than (±) 40% for fundamental events 6 and 7 can be acceptable if no MSD have to be calculated for larger and/or adult patients (with thicknesses equivalent to 25 and 30 cm PMMA, respectively).
- Deviation of more than (±) 40% for fundamental events 8 and 9 can be acceptable if no MSD have to be calculated for thin and/or paediatric patients (with thicknesses equivalent to 15 and 10 cm PMMA, respectively).
- Deviation of more than (±) 40% for fundamental event 14 is acceptable if no lateral projections are used or if the exposure from lateral projections can be neglected. A data collection sheet is provided in Annex 3: data collection template.

The maximum deviation value (40%) is suggested based on combination of the measurement uncertainty (from approximately 5% to more than 10%, depending on the type of dosimeter) and the maximum deviation of the displayed air kerma-area product (P_{KA}) value (35%) as adopted by the European Commission guidelines (EC, 2012). Since the P_{KA} or the $K_{a,r}$ are the basic input parameters for

[2] No MSD is calculated nor measured for irradiation events 1 to 4; those irradiations are aimed at assessing the accuracy of the displayed $K_{a,r}$ and the effect of the table and mattress attenuation.

the MSD calculations, the proposed value of the MSD maximum deviation should be at least equal to the maximum deviation of the P_{KA} recommended by the EC. A more stringent value could be adopted locally if appropriate.
A conservative estimate (overestimation) of the MSD is more appropriate for radiation protection purpose; however, this is not translated into the acceptability criteria.

F. Frequency

The Acceptance protocol should be performed post installation and prior to releasing the SDC software product into clinical use.

V. Quality control protocol

A. Introduction

This QC protocol is to be performed on a regular basis. Ideally it should become an element of the routine QC assessment of the angiography systems. If not, the authors recommend to perform the QC of the SDC tools at least once a year.
The QC protocol is a shortened version of the Acceptance Protocol. Instead of 13 fundamental irradiation set-ups performed on various phantom thicknesses and 3 clinical procedures, the QC protocols is only composed of 8 fundamental set-ups and a single phantom thickness.
Due to restricted/limited access to desired technical settings, it may be challenging to test the system. Some creativity and flexibility are therefore necessary when performing the protocol.

B. Material

1. Dosimeters

Adequately calibrated TLDs, gafchromic films or QC dosimeter can be used depending on availability. It should be noted that most QC dosimeters, do not respond to backscatter radiation. If such dosimeters are used, the displayed doses should be corrected for backscatter contribution as described below in section Deviation of the measured MSD.
If the dosimeters are calibrated in air kerma, the measured doses need to be converted to kerma into tissue or water so that a comparison with the skin dose calculations of SDC software can be made as per equations 1 and 2.
Many QC dosimeters do not respond to backscatter radiation. In this case, the displayed doses should be corrected for backscatter contribution following equation 2.

2. Phantoms

PMMA plates (e.g. 5 plates of 5 cm thickness, 30 x 30 cm^2 surface) are required in order to build a phantom of 25 cm representing a large adult patient.

3. Lead and copper sheets

Sufficient lead or copper sheets are put in front of the image detector in order to generate the desired tube voltage (kVp) for the $K_{a,r}$ measurements performed in the automatic brightness/exposure control mode. If the tube voltage settings can be selected in engineer mode, lead and copper sheets are not necessary.

4. Dose report

The dose report or the radiation dose structured report (RDSRs) should also be transferable if the skin dose calculations are to be performed using post-procedure software tools which are not connected to the modality or the PACS.

C. Experimental setup

The experimental set-up is reported in Table 3. The QC protocol is based on the Acceptance protocol and uses (i) a limited number of fundamental irradiation configurations (8 instead of 13) and (ii) and only **25 cm thick PMMA slab phantom**. The patient to be registered in the system is thus **170 cm and 80 kg** for all irradiation events of the QC protocol. The numbering of the irradiation events is kept from Table 1 in the Acceptance protocol.

The x-ray system to be tested should have passed routine QC tests in accordance with national requirements. If fundamental irradiation set-ups 1 to 4 have already been performed as part of the system routine QC tests, they do not need to be repeated.

The dedicated sections of the Acceptance protocols can be used without modification for the Registration of a new examination/patient, Geometry of the irradiations, Dosimeters and Selection of the examination settings.

Table 3: QC protocol: Fundamental irradiation set-ups

Irradiation event	Purpose of measurement	Configuration	Projections	Tube potential	Age (years)	Height (cm)	Weight (kg)
1[1,2]	$K_{a,r}$ calibration	Free in air	PA	low (~80 kVp)	NA	NA	NA
2[1,2]	$K_{a,r}$ calibration	Free in air	PA	high (~120 kVp)	NA	NA	NA
3[1]	Effect of the mattress and table attenuation	On mattress + table	PA	low (~80 kVp)	NA	NA	NA
4[1]	Effect of the mattress and table attenuation	On mattress + table	PA	high (~120 kVp)	NA	NA	NA
6[3]	Effect of the phantom scatter; thicker patient	Phantom 25 cm + mattress + table	PA	Automated selection	Adult	170	80
11[4]	Effect of field overlap	RA Phantom + mattress + table	PA + LAO 20	Automated selection	Adult	170	70
12[4]	Effect of field overlap	RA Phantom + mattress + table	PA + LAO 20 + PA CRAN 15	Automated selection	Adult	170	70
13[4]	Effect of lateral irradiations	RA Phantom + mattress + table	LLAT or RLAT	Automated selection	Adult	170	70

[1] No MSD is calculated nor measured for those irradiation events

[2] Lateral irradiations (LAO or RAO90) can be used instead of PA if the phantom is positioned perpendicularly to the table.

[3] Except for dosimeters which do not respond to backscatter, such as most QC dosimeters

[4] A 25 cm thick PMMA slab phantom can be used if no RA phantom is available.

D. Acceptability criteria

As per the Acceptance protocol, the calculated MSD values should **not differ more than 40% from the measured values** for any of the fundamental irradiations events 6, 11, 12 and 13[3]. Deviation of more than (±) 40% for fundamental event 6 can be acceptable if no MSD have to be calculated for larger and/or adult patients (with thicknesses equivalent to 25 cm PMMA or more, respectively).
In addition, the deviation of the calculated MSD values should not deviate more than (±) 25% from the acceptance testing baseline.

E. Frequency

It is recommended to perform the QC protocol for SDC systems at least once per year (or following the frequency of the angiographic system QC) and following any major software upgrade. The Service Engineers should advise the local physicists if this is necessary.

VI. Accuracy of the skin dose calculation software tools

A. Introduction

In order to assess the accuracy of existing SDC software, measurements following the Acceptance protocol as per section IV, were made on one angiographic system from each of the four main vendors. Gafchromic films, QC dosimeters and TLDs were used for the measurements.

B. Material

1. Angiographic systems

Measurements were performed following the Acceptance protocol a Canon Infinix CF-i biplane, a GE Innova IGS 540, a Philips Allura Xper and a Siemens Artis Zee biplane. Details of the systems are given in Table 4. Only the main tube was tested on biplane systems.

Table 4: angiographic system characteristics

Manufacturer	Model	Installation year	FOV values[1] (cm)	Distance source-to-IRP (cm)	Inherent filtration (mmAl)	National regulatory QC
Canon	Infinix CF-i biplane[2]	2017	12; 17; 20	55	3.3	Passed
GE	Innova IGS 540	2013	16; 20; 32; 40	57	3.5	Passed
Philips	Allura Xper	2011	15; 20; 25	61.5	3.7	Passed
Siemens Healthlineers	Artis Zee biplane[2]	2015	11;16; 22; 32;42;48	60	3	Passed

[1] reported FOV values are field diagonal for Philips and Siemens systems, and field side for Canon and GE systems ; [2] Only main tube tested.

[3] No MSD is calculated nor measured for irradiation events 1 to 4; those irradiations are aimed at assessing the accuracy of the displayed $K_{a,r}$ and the effect of the table and mattress attenuation.

2. Skin dose calculation software tools

Skin dose estimates were performed with 9 SDC software products: CareMonitor, Siemens, Germany; DOSE by Qaelum (referred as DOSE in the rest of this document), Qaelum, Belgium; DoseMap, GE, France; Dose Tracking System (DTS), Canon, USA; em.dose, Esprimed, France; OpenSkin, England; Radiation Dose Monitor (RDM); DoseWatch Skin Dose Map (referred to as SDM in the rest of this document), GE, France; and SkinCare, Serbia. Although CareMonitor calculate the maximum accumulate $K_{a,r}$, thus not accounting for the table and mattress attenuation nor for the radiations scattered by the patient, it was included in the study. All software but CareMonitor produced a map of the skin dose distribution. The maps produced by DoseMap, however, were accidentally erased from the PACS and could not be retrieved. The SDC software products were tested in default mode. It means that system-specific parameters were not input in the software tools if not available in the RDSR[4]; default values were used instead. The version of the SDC software solutions and the specific values of the user settings used for the MSD calculations are presented in Table 5. An extended description of the software products, their capabilities and the calculation settings is available in the first deliverable of the present project (Malchair et al 2018). Two versions of SDM were used: a commercial version implementing the ICRP voxel phantom (referred as SDM ICRP in the rest of this document) and a research version implementing a flat phantom (referred to as SDM flat in the rest of this document). Results of both software solutions are presented separately.

RDSRs were extracted in the ".dcm" format after each irradiation event described in the Acceptance protocol, and after each clinical procedure to be used as input for offline SDC software. Since OpenSkin and em.dose could not handle RDSR data in the ".dcm" file format, a locally developed Python script was used to convert the RDSR files into ".txt" or ".csv" files.

Not all SDC products could be combined with the four angiographic units used for the measurements. Indeed, CareMonitor, DTS and DoseMap were vendor-dependent, meaning they could only be used on an angiographic system of the same vendor; while other SDC products could only be used with angiographic systems from two or three vendors. Only three products (OpenSkin, em.dose and SkinCare) were used with angiographic systems from the four vendors; em.dose and OpenSkin were specially modified for the present project in order to allow skin dose estimates for Philips and Canon angiographic units. SDM was compatible with all vendors but was not used with the Canon system. DTS and DoseMap were the only solutions which could display the MSD and the dose map online.

[4] Except for the online products which extract the calculation input from the modality.

Table 5: Characteristics of the skin dose calculation software solutions and specific values of the user settings used for the MSD calculations

Name	Manufacturer/ Developer	Version	User settings	Patient model	Tested with	Comments
CareMonitor	Siemens	Unknown	Unknown	Unknown	Siemens	- Vendor-dependent. - Online solution
Dose	Qaelum	19.11	- Patient model - $K_{a,r}$ correction factor= 1 - Mattress thickness =4 cm - Table equivalent thickness = 1.65 mmAl	Scalable elliptical phantom	GE, Philips, Siemens	
DoseMap	GE	Innova IGS 540 M4017064	- Patient model - Adult local dose threshold = 2 Gy - Mattress thickness = 5 cm	Scalable elliptical phantom "single model"	GE	- Vendor-dependent - Online solution
Dose-Tracking System (DTS)	Canon[1]		- Patient model	Caeser voxel phantom (under 84 kg model)	Canon[1]	- Vendor-dependent - Online solution
em.dose	Esprimed	Modified[2]	- Patient model - $K_{a,r}$ correction factor= 1 - Table/mattress attenuation= 20% - Table and mattress thickness =2.5 cm	Flat	Canon[1], GE, Philips, Siemens	- Compatible with all vendors - Code modified to handle Canon and Philips systems (Source-floor distance set as 41 cm and 26 cm, respectively)
OpenSkin	Cole J., London, England	Modified[2]	- Patient model - Mattress thickness = 0 cm - Table thickness = 2 cm	Flat	Canon[1], GE, Philips, Siemens	- Compatible with all vendors - Code modified to handle Canon and Philips systems – (Source-floor distance set as 41 cm and 30 cm, respectively)
Radiation Dose	Medsquare	1.4.4	- Patient model - $K_{a,r}$ correction factor= 1	Rectangular parallelepiped	GE, Siemens	

Monitor (RDM)			- Table/mattress attenuation= 10% - Mattress thickness = 2 cm - Table thickness = 0.5 cm	with two half-cylinders on the side		
Skin Dose Map (SDM)	GE	Versions >= 3.1.2	- Patient model - $K_{a,r}$ correction factors[2] = 1 - Mattress thickness = 4 cm - Table equivalent thickness = 0.14 mmAl - Distance table to head = 10 cm	- Flat[3] - ICRP voxel phantom[4]	GE, Philips, Siemens	- Compatible with all vendors
SkinCare	Krajinović M., Belgrade, Serbia		- Patient model - $K_{a,r}$ correction factor= 1 - Table/mattress attenuation= 20%	Anthropomorphic voxel phantom	Canon[1], GE, Philips, Siemens	- Compatible with all vendors

[2]software specifically modified for the project; [2]correction factors available for fluoroscopy and acquisition modes; [3]referred to as SDM flat in the text; [4]referred to as SDM ICRP in the text.

3. Dosimeters

To make the most of the properties of each dosimeter types, they were used as reference measurement device for different irradiation settings. QC dosimeters were used as reference for assessing the accuracy of the $K_{a,r}$ displayed by the angiographic systems (irradiation events 1 to 4). TLDs were used to estimate the accuracy of the SDC software tools when different phantom thicknesses were used (events 5 to 10 and 13) and when limited number of overlapping projections were used (events 11 and 12). Gafchromic films were used to detect the MSD of the clinical procedures (Table 2) and produce dose maps.

All TLDs were circular pellets of 4.5 mm diameter and 0.9 mm thickness and manufactured with LiF:Mg,Cu,P material (MCP-N, Institute of Nuclear Physics, Poland).. Sets of 3 dosimeters were prepared for each irradiation setting. Before exposure, the TLDs were annealed 10 minutes in an oven at 240°C, followed by a fast cooling in a freezer at -10°C. Two sets of 4 TLDs were used to monitor the dose accumulated during storage and transportation. After exposure and before read-out, the dosimeters were heated at 120°C in an oven for 30 minutes. The TLDs were read on a Harshaw 5500 system with a constant rate of 10 °C/s from room temperature up to 240°C. TLD signal output was corrected for the individual sensitivity of each dosimeter, which was determined using a Cs-137 source. TLDs were calibrated using RQR-8 reference beam (IEC 2005) at CEA primary standard laboratory. Considering the standard uncertainties (k=1) associated with the energy dependence (5%) and the angular dependence (4%) as determined in the current study, along with the characteristic uncertainties of the dosimetric system used (fading (3%), the individual sensitivity (2%), the repeatability (1%), the calibration coefficients (1.4%) and the calibration doses (2.2%)), the expanded uncertainty (k=2; 95% confidence interval) was 16%.

Uncertainty budget calculation using XR-RV3 Gafchromic films was used following the scenarios suggested by Farah et al (2015). For all different steps except uncertainties related to film, the scenario A was used as the dose delivery was done in a primary calibration laboratory (CEA), and the methodology was followed closely with enough sampling. Scenario B was taken into account for the uncertainties related to film (Darkening over time, Film orientation, Humidity and temperature during transportation and storage) as the films could not be scanned at exactly the same number of days after irradiation, the orientation was not written on all films and most importantly they were sent through postal services. The uncertainty description and its estimate are provided in Table 6. Based on this uncertainty budget calculation, the expanded standard uncertainty (k=2; 95% confidence interval) was 26% for film measurements.

Table 6 Uncertainty budget for XR-RV3 Gafchromic films

Uncertainty Description	Estimate (%)
Dose delivery uncertainty	
Air kerma rate measurements	0.8
Setup error and film positioning	0.1
Beam uniformity	0.3
Scanner-related uncertainty	
Scan uniformity	0.3
Short term stability	0.1
Long term stability	1.5
Scanner readout warm-up and software effects	-
Uncertainties related to a film	
Inter/intra-batch uniformity	4
Darkening over time	1.5
Effect of scan light	1
Dose rate dependence	3

Radiation quality dependence	10
Film orientation	0
Humidity and temperature during transportation and storage	2
Uncertainties related to calibration	
Fitting equation	2
Dose range of calibration points	2
Number and distribution of data points	2
Reading outliers and precision of fit parameters	3
Relative combined standard uncertainty (k=1)	**13**
Relative expanded uncertainty (k=2)	**26**

Three models of solid-state QC dosimeters were used for the measurements. An X2 and a X2 solo (both from Raysafe, Bildal, Sweden) were used for the measurements on the GE and the Canon systems, respectively. An Accu-Gold (Radcal, Monrovia, USA) was used for the measurements on the Philips and GE systems. All three dosimeters were calibrated using RQR-8 reference beam at CEA primary standard laboratory. Their energy response was also characterised for beam qualities representative of IC. A conservative estimate of the expanded measurement uncertainty of 7% (k=2) was obtained. This includes the energy dependence (3%, k=1), the angular dependence (±3% of variation of response in the range of angles of ±5 degrees).
TLD and gafchromic film measurements performed for irradiations events 5 to 13 and during the clinical procedures were converted to dose in water by multiplying the reported doses by the ratio of mass energy-absorption coefficients, $f_{air,water}$. A single value of 1.06 was used.

C. Results

1. Fundamental irradiations

a) Calibration (events 1 to 4)

The results of the tests of the displayed $K_{a,r}$ accuracy are reported in Table 7. For all the systems tested, the accuracy of the displayed $K_{a,r}$ without table or mattress in the field (irradiation events 1 and 2) was within 25% of the values measured with the QC dosimeters. The displayed $K_{a,r}$ overestimated the measured values in air in all cases but on the Canon system at high tube voltage (irradiation event 2). When the table and the mattress were in the x-ray field (irradiation events 3 and 4), the accuracy of the displayed $K_{a,r}$ was within 35% for the Philips and the Canon systems, and within 90% for the GE and Siemens systems. The displayed $K_{a,r}$ overestimated the measured values in all cases. Those results correspond to table and mattress transmission factors[5] ranging from 54% to 89% at low tube voltage and from 69% to 90% at high tube voltage.

Table 7: Accuracy measurements of the displayed K values. The $K_{a,r}$ accuracy is calculated as displayed $K_{a,r}$ divided by measured $K_{a,r}$ using QC dosimeters. The transmission factor is reported in parenthesis.

Irradiation event	Tube voltage	Configuration	Displayed $K_{a,r}$ accuracy (Transmission factor)			
			GE	Philips	Siemens	Canon
1	low (~80 kVp)	Free in air	111%	115%	100%	113%
2	high (~120 kVp)	Free in air	106%	107%	121%	92%
3	low (~80 kVp)	Table & mattress	172% (64%)	130% (89%)	186% (54%)	133% (85%)
4	high (~120 kVp)	Table & mattress	151% (70%)	119% (90%)	175% (69%)	117% (78%)

[5] which is the ratio of the $K_{a,r}$ measured in air and the on the top of the table and mattress

b) PMMA slab phantom (events 5 to 9)

The MSD for PMMA phantom thicknesses ranging from 10 to 30 cm are reported in Figure 5 to Figure 4 for GE, Philips, Siemens and Canon systems, respectively. The MSD estimates are normalised to the doses measured with TLD. Tube voltage (kVp) and HVL values (mmAl) of the irradiation are reported in the same figures.

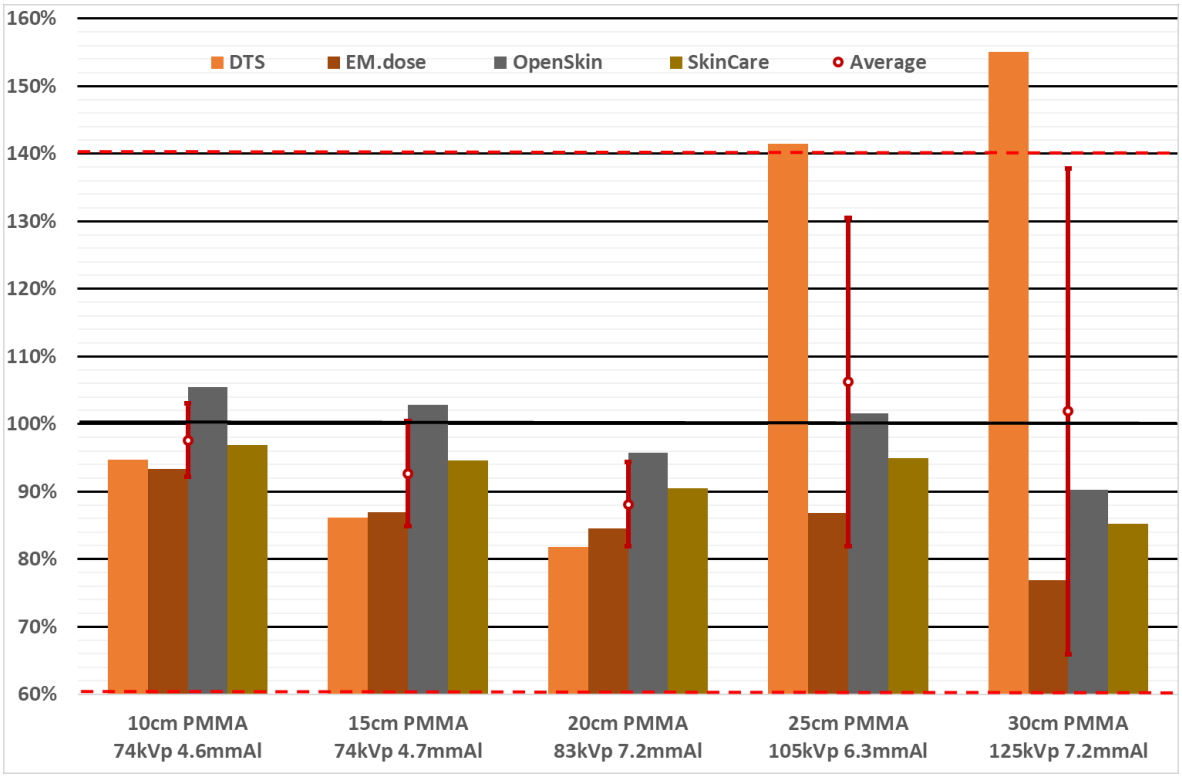

Figure 4: MSD estimated using SDC software tools for PMMA thicknesses ranging from 10 to 30 cm on a Canon Infinix CF-i biplane system; MSD estimates are normalised to measured doses. Tube voltage (kVp) and HVL values (mmAl) of the irradiation are reported on the second line of the horizontal axis. Red horizontal bars represents the ±40% deviation range as per the acceptability criteria of the Acceptance protocol; the COV is represented as error bars drawn from the average MSD estimate.

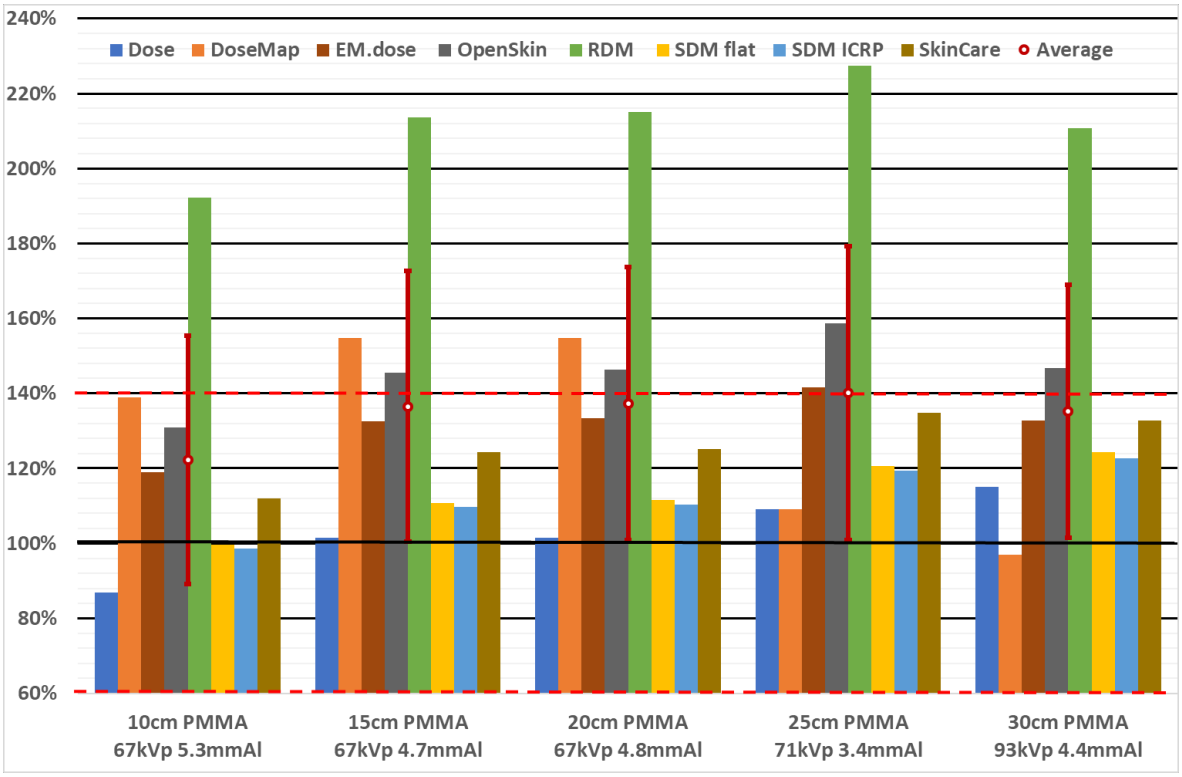

Figure 5: MSD estimated using SDC software tools for PMMA thicknesses ranging from 10 to 30 cm on a GE Innova IGS 540 system; MSD estimates are normalised to measured doses. Tube voltage (kVp) and HVL values (mmAl) of the irradiation are reported on the second line of the horizontal axis. Red horizontal bars represents the ±40% deviation range as per the acceptability criteria of the Acceptance protocol; the COV is represented as error bars drawn from the average MSD estimate.

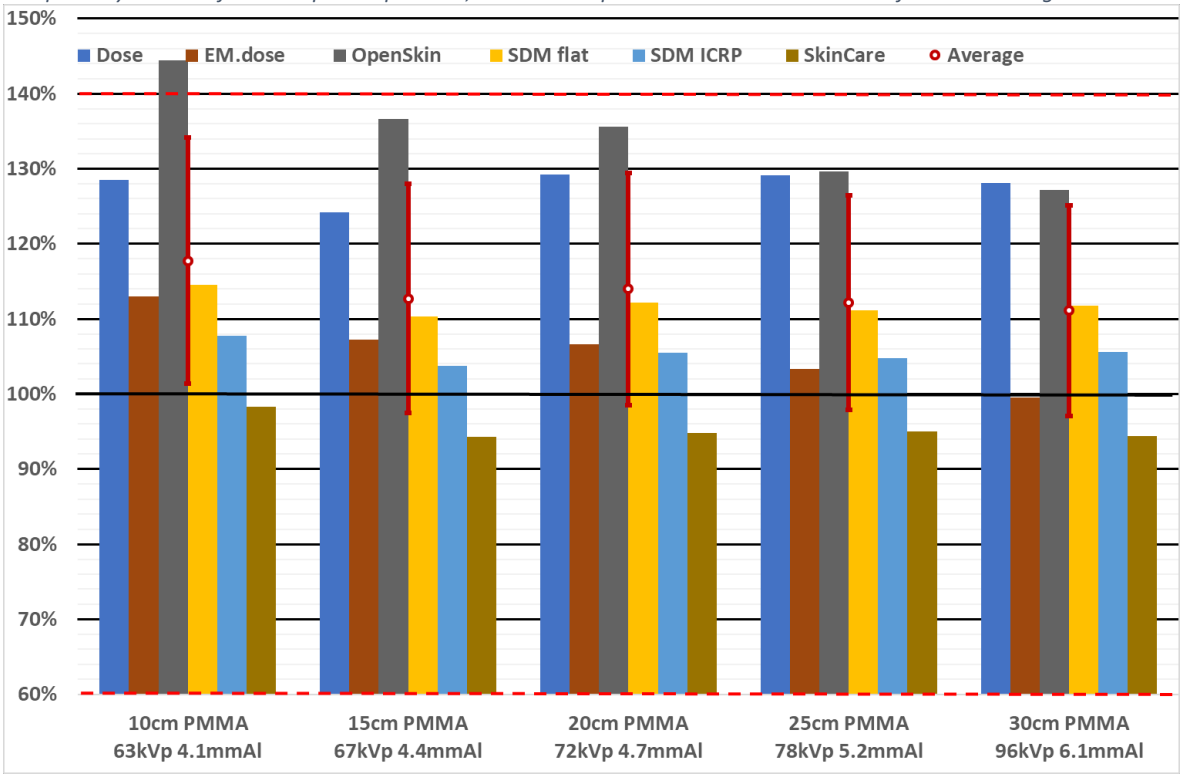

Figure 6: MSD estimated using SDC software tools for PMMA thicknesses ranging from 10 to 30 cm on a Philips Allura Xper system; MSD estimates are normalised to measured doses. Tube voltage (kVp) and HVL values (mmAl) of the irradiation are reported on the second line of the horizontal axis. Red horizontal bars represents the ±40% deviation range as per the acceptability criteria of the Acceptance protocol; the COV is represented as error bars drawn from the average MSD estimate.

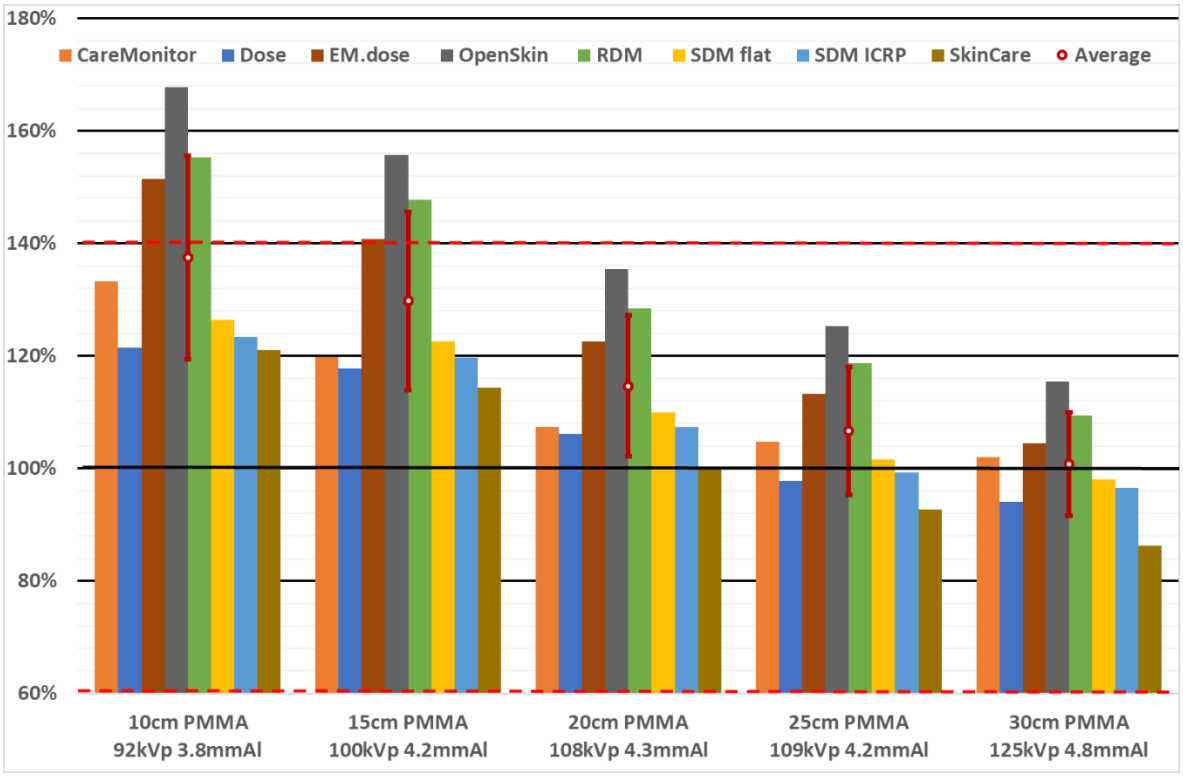

Figure 7: MSD estimated using SDC software tools for PMMA thicknesses ranging from 10 to 30 cm on a Siemens Artis Zee biplane system; MSD estimates are normalised to measured doses. Tube voltage (kVp) and HVL values (mmAl) of the irradiation are reported on the second line of the horizontal axis. Red horizontal bars represents the ±40% deviation range as per the acceptability criteria of the Acceptance protocol; the COV is represented as error bars drawn from the average MSD estimate.

A few SDC products provided MSD estimates within the 40% acceptability limit for all phantom thicknesses on the compatible systems: SkinCare (on all four angiographic systems), Dose, SDM flat and ICRP (on all systems but Canon), CareMonitor (on Siemens system). em.dose performances were nearly comparable, significantly exceeding the 40% criterion for the 10 cm phantom on the Siemens system only. Results from OpenSkin (on four systems), RDM (on GE and Siemens) and DoseMap and DTS (on GE and Canon, respectively) are more variable and could exceed the acceptability criterion for thicknesses between 20 and 25 cm, which should cover numerous patients in IC. The coefficient of variation (COV) of the MSD estimates for a specific phantom thickness was small for Philips (ranging from 14% to 16%) and Siemens systems (9% to 18%), which indicates that most software provided comparable estimates. The COV was larger for the GE (33% to 39%) and Canon systems (5% to 36%). This was mostly due to RDM outlying values for the GE system and DTS values for the Canon system. RDM estimates were 92% to 127% higher than the measured values on the GE system and exceeded the acceptability criterion.

c) Rando Alderson phantom (events 10 to 13)

The MSD for the irradiations of the RA phantom are normalised to the doses measured with TLDs and are reported in Figure 9 to Figure 8 for GE, Philips, Siemens and Canon systems, respectively.

All software tended to overestimate the MSD for the GE system, except Dose. This was not the case for the Philips, Siemens and Canon systems.

A few SDC products provided again MSD estimates within the 40% acceptability limits for all RA phantom irradiations on the compatible systems: Dose and SkinCare on all four angiographic systems, DoseMap on the GE system, and CareMonitor on the Siemens system. SDM ICRP estimates were within the 40% range on all systems but Canon except for the lateral irradiations which were strongly overestimated (225% on GE and 166% on Philips). Similarly, DTS estimates were within 40% of the measured doses on the Canon system except for the lateral irradiations. The remaining software

products (em.dose, OpenSkin, RDM and SDM flat) could not provide MSD estimates for the lateral irradiation. Nevertheless, their accuracy was good for the three other irradiations performed on the RA phantom, except for RDM. RDM estimates were again outlying and overestimating the measured dose on the GE system. The COV of the MSD estimates on the RA phantom (excluding the lateral irradiations) was rather small for the Philips and Siemens systems (Philips 9% to 13%; Siemens 10% to 11%). The COV was larger for the GE and Canon systems (GE 14% to 22%; Canon: 7% to 34%), mainly owing to the discrepant response of RDM and DTS, respectively.

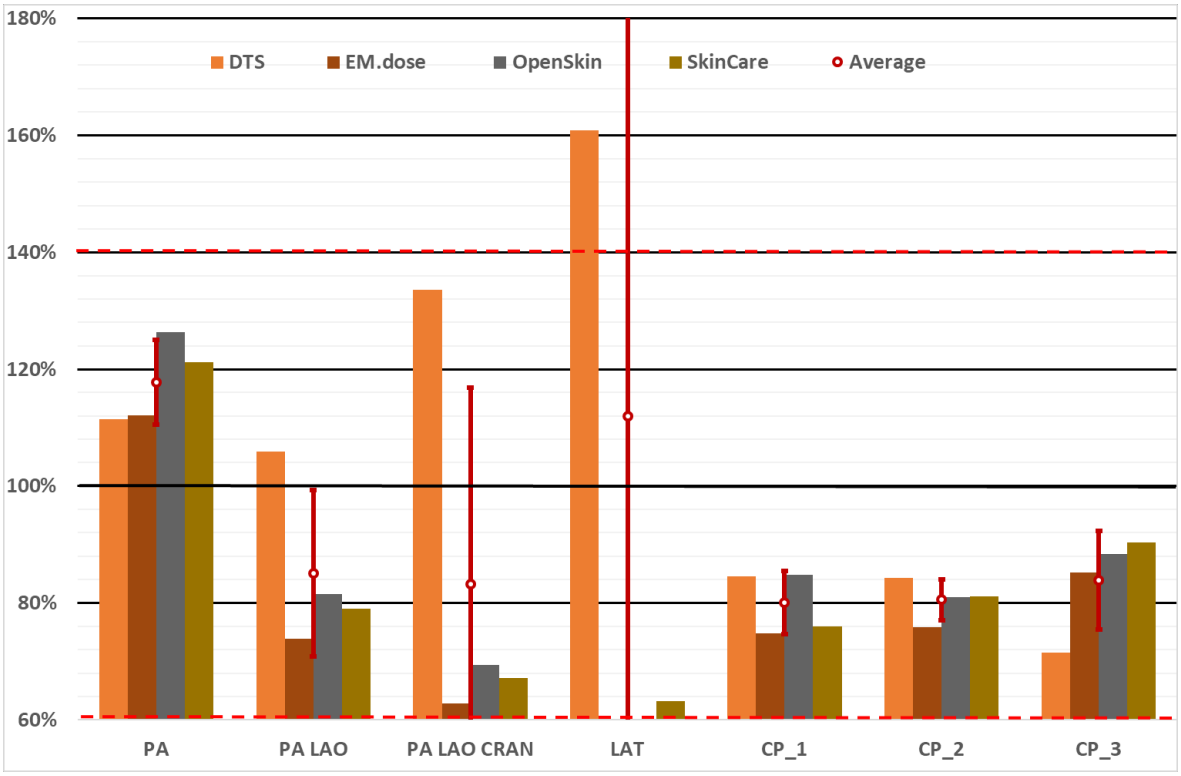

Figure 8: MSD estimated using SDC software tools for fundamental irradiations events 10 to 13 and clinical procedures (CP) 1 to 3 of a RA phantom on a Canon Infinix CF-i biplane system; MSD estimates are normalised to measured doses. PA, PA LAO, PA LAO CRAN and LAT refers to the projections used for the irradiation events 10 to 13, respectively. Red horizontal bars represents the ±40% deviation range as per the acceptability criteria of the Acceptance protocol; the COV is represented as error bars drawn from the average MSD estimate.

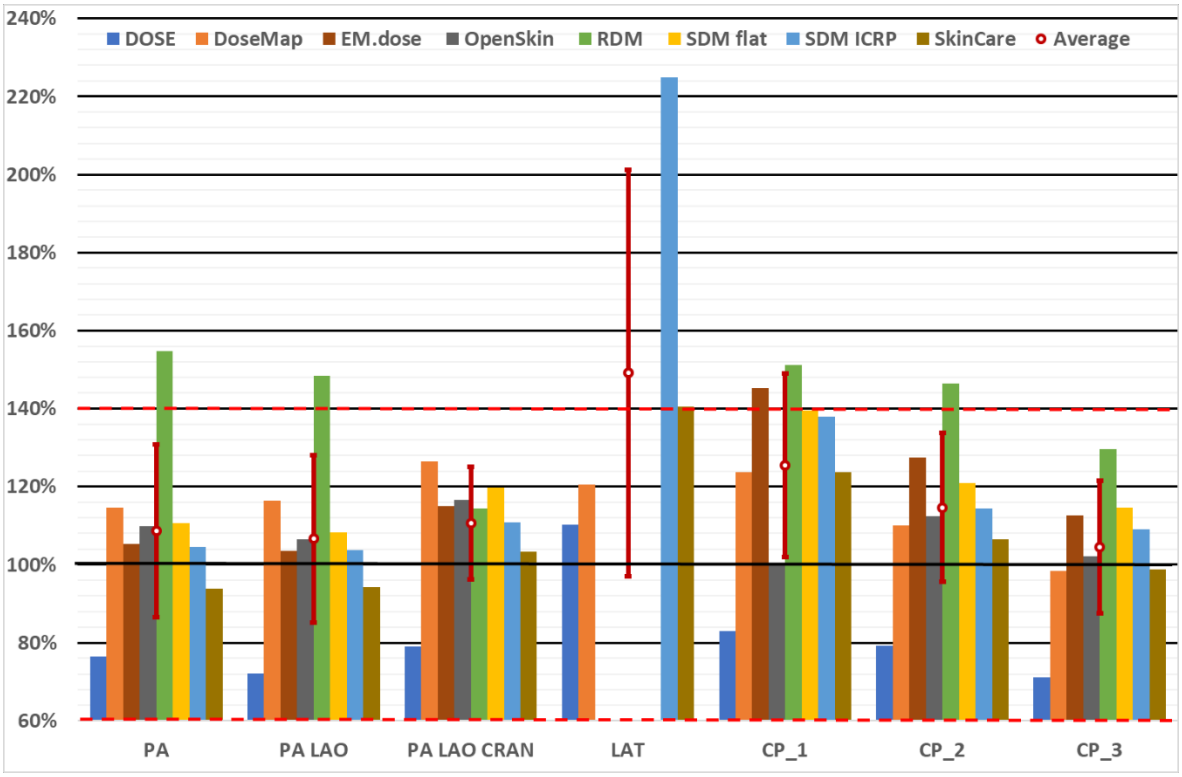

Figure 9: MSD estimated using SDC software tools for fundamental irradiations events 10 to 13 and clinical procedures (CP) 1 to 3 of a RA phantom on a GE Innova IGS 540 system; MSD estimates are normalised to measured doses. PA, PA LAO, PA LAO CRAN and LAT refers to the projections used for the irradiation events 10 to 13, respectively. Red horizontal bars represents the ±40% deviation range as per the acceptability criteria of the Acceptance protocol; the COV is represented as error bars drawn from the average MSD estimate.

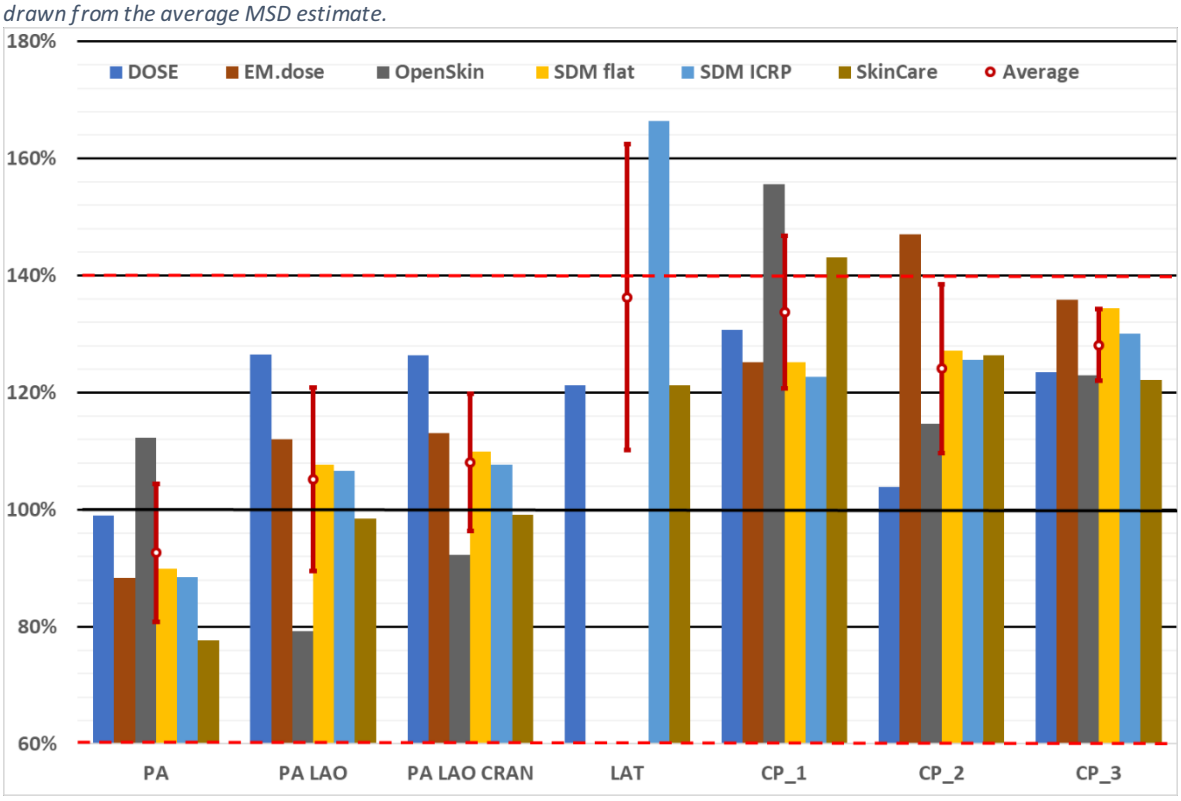

Figure 10: MSD estimated using SDC software tools for fundamental irradiations events 10 to 13 and clinical procedures (CP) 1 to 3 of a RA phantom on a Philips Allura Xper system; MSD estimates are normalised to measured doses. PA, PA LAO, PA LAO CRAN and LAT refers to the projections used for the irradiation events 10 to 13, respectively. Red horizontal bars represents the ±40% deviation range as per the acceptability criteria of the Acceptance protocol; the COV is represented as error bars drawn from the average MSD estimate.

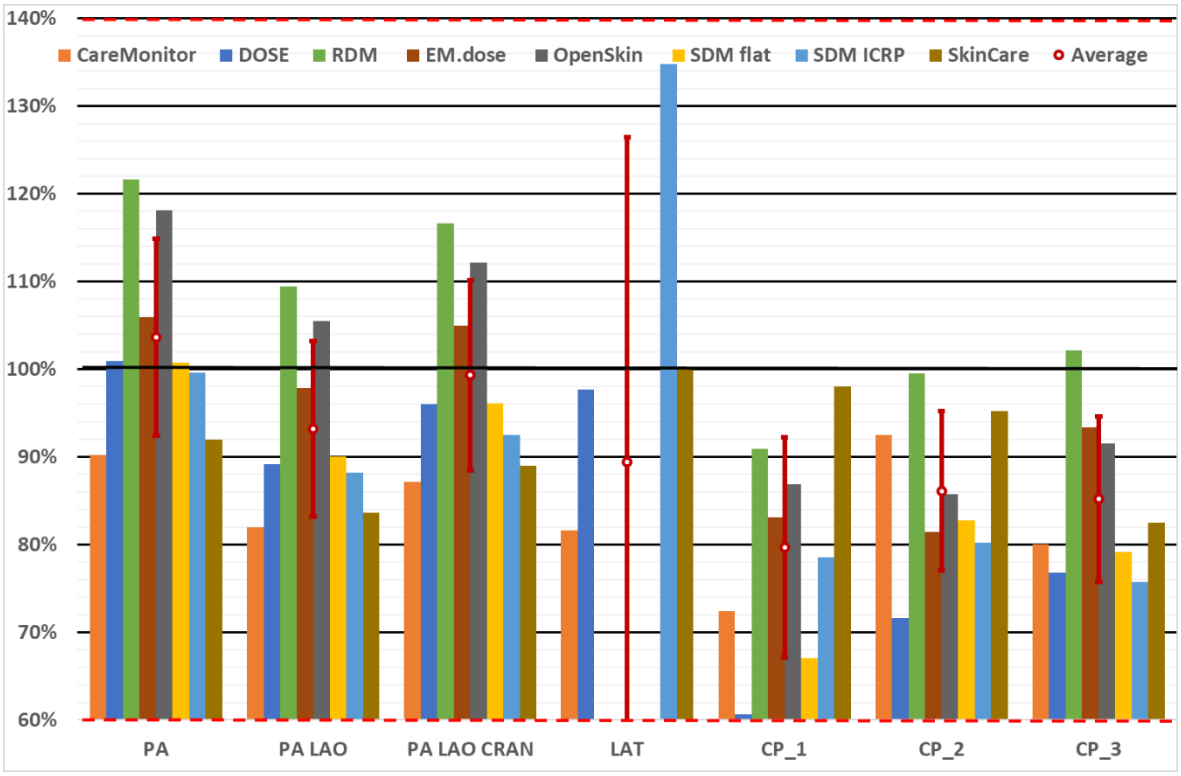

Figure 11: MSD estimated using SDC software tools for fundamental irradiations events 10 to 13 and clinical procedures (CP) 1 to 3 of a RA phantom on a Siemens Artis Zee biplane system; MSD estimates are normalised to measured doses. PA, PA LAO, PA LAO CRAN and LAT refers to the projections used for the irradiation events 10 to 13, respectively. Red horizontal bars represents the ±40% deviation range as per the acceptability criteria of the Acceptance protocol; the COV is represented as error bars drawn from the average MSD estimate.

2. Clinical procedures

a) Maximum skin dose accuracy

The MSDs calculated for the three clinical procedures on the RA phantom are normalised to the doses measured with gafchromic films and are reported in Figure 9 to Figure 8 for GE, Philips, Siemens and Canon systems, respectively.

The MSDs estimated by most SDC software products were within ±40% of the clinical procedure measurements, except for em.Dose on GE and RDM on GE and Siemens. All the estimates were within 40% on the Philips and Canon systems.

The variability of the MSD estimates by different SDC software for a clinical procedure on a specific system was smaller than for the PMMA irradiations. Across the three procedures, the COV ranged between 17% to 24%, 6% to 14%, 9% to 13%, 3% to 8% on the GE, Philips, Siemens and Canon systems.

The accuracy of a specific software tool was quite constant across the three procedures performed on the Siemens and Canon systems. Variation in accuracy was within 20% and 14%, respectively. The variation was greater on the GE and Philips systems, with accuracy variation within 33% (and 41%, respectively.

b) Dose map accuracy

The dose maps measured with the gafchromic films, as well as the dose maps produced by the SDC software tools are reported in Annex 2: clinical procedures. Maps from the measurements performed on the GE, Philips, Siemens and Canon systems are reported in Figure 14 to Figure 13, respectively.

All maps followed identical map orientation, with patient's head pointing towards the top of the maps and patient's left side pointing towards the left side of the maps. The only exception was Dose with patient's right side pointing towards the left side of the maps. em.dose maps did not show identical scales in horizontal and vertical directions. Colour choice was rather uniform. Warmer colours were used to indicate higher doses, except for OpenSkin which was used in grey level mode. Thanks to the use of multicolour scales, some maps depicted the dose distribution with more clarity than the gafchromic films. The colour scale was not adapted to the magnitude of the displayed MSD on maps from Dose, DoseWatch, DTS and OpenSkin.
The different patient representations, colour scales and resolutions made a quantitative comparison challenging. Limited modifications (such as cropping or reorientation) of the dose maps as created by SDC software were therefore performed in order to facilitate a qualitative comparison. From a qualitative, visual comparison, it appears that all maps more or less reproduced the dimensions and the relative position of the region of the MSD on the GE and Siemens systems accurately. An exception was OpenSkin's first procedure maps, which show an excessive distance between the two central high-dose regions as measured with the films. The situation was more contrasted for the procedures performed on the Philips systems. The shape and size were off for all software, whereas the relative position of the MSD region was correct (except for SkinCare which depicted the MSD at the intersection of two fields not overlapping in the measured map). For the Canon system, all software tools adequately reproduced the relative position and the shape of the MSD region, except for SkinCare lacking the high dose region at the overlapping intersection of two irradiation fields.

D. Discussion

Measurements following the Acceptance protocol for testing the accuracy of the SDC software tools were performed on four angiographic systems from GE, Philips, Siemens and Canon.
The first measurements (irradiation events 1 to 4) confirmed that the $K_{a,r}$ of all systems was within the accuracy limits of the national and European regulations. The accuracy of the displayed $K_{a,r}$ was better without the table and the mattress in the field. This indicates that all vendors calibrated their systems free in air. This is in agreement with information provided by the vendors about the calibration methods. Since the calculated MSD is directly proportional to the displayed $K_{a,r}$ and most SDC software uses free-in-air calibrated $K_{a,r}$ as the main calculation input, the accuracy of the $K_{a,r}$ and the calibration conditions (free-in-air or on the table, possibly with the mattress) are crucial information for MSD estimates since the attenuation factor of the table is used by most SDC software to calculate the Kerma at the patient entrance (Malchair et al 2018). The considerable spread of transmission factors among angiographic systems is not new (e.g., DeLorenzo et al 2019) and stresses the importance of using measured transmission values rather than default one in order to increase further the accuracy of the MSD estimates. In addition, the table transmission characteristics are also worth considering when comparing dose indicators such as $K_{a,r}$ or P_{KA} values from different systems.
MSDs were measured on PMMA slab phantoms of 5 different thicknesses (irradiation events 5 to 9) and a RA phantom exposed with 4 beam angulations (irradiation events 10 to 13) and during three clinical procedures. MSD estimates were then calculated, using at least 4 SDC tools on Philips and Canon angiographic systems, and up to 8 for GE and Siemens systems. This greater software compatibility with GE and Siemens systems can obviously be seen as a tendency from the software developers to produce tools targeting systems from the most common manufacturers. From discussions with some developers, this can also be related to the fact that GE and Siemens define the table height with respect to the system isocentre (Malchair et al 2018). The distance between the table top and the x-ray source can therefore be calculated using only non-private fields from complete RDSRs. For Philips and Canon systems, the determination of the distance between the table top and the x-ray source is more complex because the table height is defined with respect to the floor;

measurements or RDSR private fields are thus necessary to determine the distance x-ray source to table top accurately.

All software tended to overestimate the MSD measured with the 5 PMMA thicknesses for GE, Philips and Siemens systems. In general, the higher difference observed between MSD measurements and calculations can be partly explained by the use of default SDC software settings. Most software used a $K_{a,r}$ correction factor of 1 as default value while the actual correction factor was smaller (Table 7: Accuracy measurements of the displayed K values. The $Ka_{,r}$ accuracy is calculated as displayed $Ka_{,r}$ divided by measured $Ka_{,r}$ using QC dosimeters. The transmission factor is reported in parenthesis. Table 7), resulting in an overestimation of the MSD. The low transmission factor of the GE and the Siemens systems (Table 7) also explained part of the overestimation since the default table and mattress transmission values set in the SDC software were higher (Table 5) in most cases. Nevertheless, a conservative estimate of the MSD is preferable from a radiation protection point of view. The opposite is observed for the Canon system, with most MSD estimates underestimating the measured doses.

Surprisingly, CareMonitor estimates were within 40% of the measured doses, although that software solution only provides an estimate of the maximum cumulative $K_{a,r}$. The rather good agreement between the maximum cumulative $K_{a,r}$ and the MSD is likely due to the competing effects of the attenuation effect of the table and mattress and the backscattered radiations, as demonstrated by the increased software accuracy for higher PMMA thicknesses (and thus higher BSFs).

On the Siemens system, there was a clear decrease in the value of the MSD estimates from all SDC products when the PMMA phantom thickness increased; however, on the Philips system, no such effect could be observed. The MSD estimates (except estimates from OpenSkin) remained nearly constant irrespective of the phantom thickness. Those trends could be partly explained by the variation of the table and mattress transmission factors as function of the tube voltage and the HVL. For the Philips system, no significant variation of the transmission factor was measured, while for the Siemens system there was a noticeable increase (from 54% to 69%). On the GE and the Canon systems, no such general observation could be made.

When considering the MSD estimates of a specific SDC product on multiple angiographic systems, no clear trend between the phantom thickness and the MSD accuracy could be observed. For instance, the accuracy of SDM (flat and ICRP) estimates seemed to be stable irrespective of the phantom thickness on the Philips system, while accuracy increased as the phantom thickness increased on the Siemens system; and inversely on the GE system.

Results of the PA irradiations of the RA phantom (event 10) were expected to be similar to the irradiations of PMMA thicknesses of about 20 and 25 cm (events 8 to 9). This was only observed on the Siemens system. This could be due to differences in material composition and in equivalent thicknesses resulting in different tube voltage and filtration. Indeed, PMMA is not exactly tissue equivalent and the RA phantom also contain lungs. Moreover, some SDC software use height and weight as input for creating the patient model. The height and weight used for the patient registration as proposed in the Acceptance protocol might therefore have caused inadequate phantom modelling by the SDC tools. Developers should implement PMMA slab phantom models, which are readily available to medical physicists, as well as the corresponding backscatter factors in their software tools These phantom models should be obviously accessible to the users.

About half of the software products (em.dose, OpenSkin, RDM and SDM flat) could not provide MSD estimates for lateral irradiations (LLAT or RLAT). For three of them (em.dose, OpenSkin and SDM flat) this is because a flat phantom was used. Among the remaining software products, SDM ICRP and DTS did provide an MSD estimate for lateral irradiations, but with low accuracy, although good accuracy was observed for all other RA phantom irradiations. This is not surprising because there is no information from the modality or from the RDSR about the x-ray-source-to-skin distance (i.e., the distance between the patient entrance surface and the x-ray source). This issue has limited effect for

PA irradiations because the uncertainty in the source-to-skin distance arises from the thickness of the - compressed - mattress which generally introduces no more than a few-cm uncertainty and hence no more than ~10 % uncertainty in the MSD estimates as illustrated in Figure 12. On the contrary, the source-to-skin distance cannot be estimated from the table height in lateral irradiations. The phantom's contour has to be used instead (Johnson et al 2011), possibly causing errors of several cm which can cause considerable errors in the MSD estimate.

As for the PMMA and the RA phantom fundamental irradiations, the MSD estimates were within ±40% of the clinical procedure measurements, except for em.Dose and RDM on GE and RDM on Siemens. All the estimates were within 40% on the Philips and Canon system.

Anthropomorphic phantoms offer the most realistic patient representation. One (SDM ICRP) of the three tested software tools implementing anthropomorphic phantoms had only one phantom available (ICRP phantom), irrespective of the patient morphology. The two remaining software tools (DTS and SkinCare), used an extended library of anthropomorphic phantoms covering different weight and morphologies. The patient matching method is based on limited patient's data (sex, size, weight and age), possibly adapted by the user. This might be very inaccurate and cause errors in the MSD calculations because the phantom dimensions are used to select the appropriate BSF and to determine the x-ray source-to-skin distance. As mentioned above, this last issue has limited effect for PA irradiations because the source-to-skin distance is defined by the table height and the mattress thickness; on the contrary, this issue is particularly important for lateral irradiations because small errors in the phantom contour affect the x-ray source-to-skin distance, and thus the MSD estimates.

In general, all maps reproduced acceptably the dimensions, the shape and the position of the region of the MSD, although some software could miss the MSD region when situated at the thin intersection of multiple fields. The dimensions and shape of the MSD region were inaccurate for all SDC software on the Philips system because wedge filters were used, while most SDC software assumes square irradiation fields. Accounting for the use of wedge filters, whose information is available in the RDSRs, would improve the dose mapping. The same map orientation was used by all software products, except for DOSE, but not all colour scales were adapted to the magnitude of the displayed MSD. This is an issue for software testing when the delivered doses are kept low, owing to time constraints, making the map difficult to read; in daily practice, however, this is not of concern because higher doses are of interest for patient monitoring.

E. Study limitations

Although carefully designed, the present study and protocols have some limitations related to the (i) the inherent properties of the dosimetric measurement systems, (ii) the calculation methodologies of the SDC tools and (iii) the limited features tested on the angiographic systems.

(i) The dosimeters were calibrated with care, but the uncertainty associated with the measurements remains significant. A detailed study of the uncertainty associated with TLDs, gafchromic films and QC dosimeters was performed in the frame of VERIDIC project and will be available in a dedicated deliverable (Blideanu V et al 2020). For TLDs and films, the energy dependence remains the dominant factor; whereas QC dosimeters usually have a considerably smaller energy dependence, however, solid state QC detectors might show a strong angular dependence.

For QC dosimeters as well as TLDs and films, an additional uncertainty arises from the calibration, which is usually performed in air kerma. To transfer the air kerma at the phantom entrance surface to water kerma (or kerma in any other medium), the energy fluence weighted ratio of mass energy-absorption coefficients is required. For this set of clinical beams, the ratio can vary between 1.02 and 1.12 (Benmakhlouf et al 2011). Using a fixed value (1.06) can lead to a maximum error of 5 % (Benmakhlouf et al 2011).

A PMMA phantom is recommended for use. This phantom is not exactly water-equivalent. As showed by Benmakhlouf et al (2013), backscatter factors (BSFs) for PMMA are between 3% to 10% higher than in the case of a water phantom. Measurements of the MSD using a PMMA phantom can thus overestimate calculations using a BSFs determined for water. The developers should incorporate PMMA slab phantom models and the corresponding BSFs in the SDC software in order to address that limitation. In addition, it would solve the issue related to the selection of the patient features (height and weight) and possibly the patient model corresponding to the PMMA phantom thicknesses.

(ii) The SDC software were mostly tested in default mode. It means that system-specific parameters, were not input in the software tools if not available in the RDSR; default values were used instead as it might the case in clinical practice. The uncertainty of the SDC calculations might be further reduced by using for each system the actual value of the compressed mattress thickness or the attenuation effect of the table. From measurements on three systems, a recent study (DeLorenzo et al. 2019) have shown that the table and mattress attenuation could range from 9% to 41%. The calculated MSD being directly proportional to the attenuation of the table and the mattress, the effect on the accuracy of the MSD calculations is evident. Aside from attenuating the beam, the mattress, which are encountered in various thickness and are compressed by the patient weight, can also cause an error in the estimate of the source-to-skin distance. As illustrated in Figure 12, considering an actual source-to-skin distance of 60 cm, an error of 1 (-1) cm, 2 (-2) cm and 3(-3) cm in the mattress thickness estimate would cause an additional error of -3 (3) %, -6 (7) % and -9 (11) % in the results of the SDC software tool, respectively. Next to those, the $K_{a,r}$ calibration factor is another parameter which can considerably influence the dose but which was usually not accounted for in the dose calculations. Although there is a specific tag for reporting the $K_{a,r}$ calibration factor it is never properly filled. Provided the 35% deviation of the displayed P_{KA} tolerated by the European Commission guidelines (EC, 2012), this can have a great effect on the calculated dose.

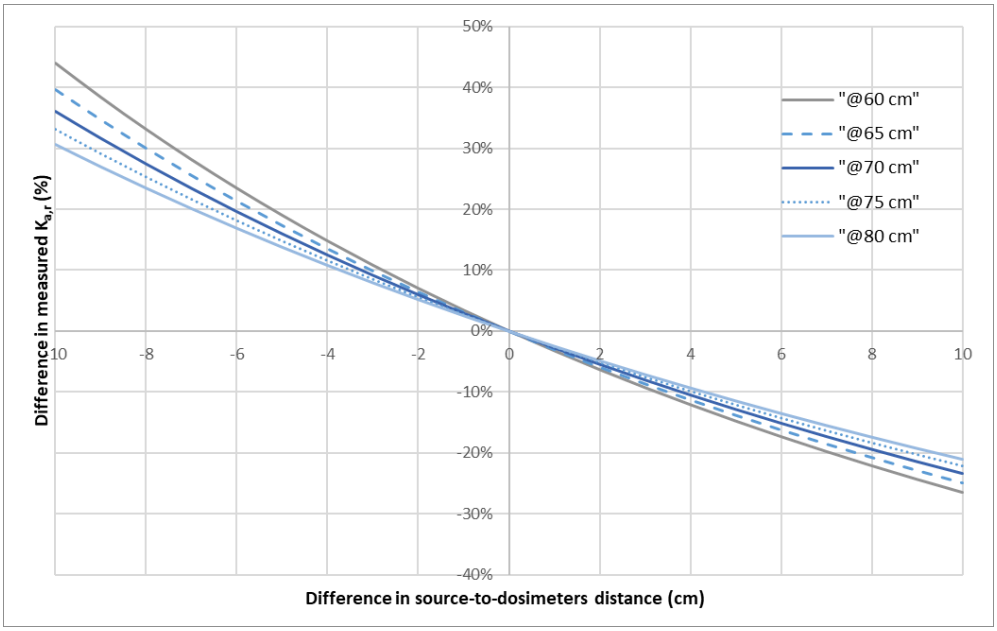

Figure 12: Difference in measured $K_{a,r}$ values (%) error in the dosimeter position. Each line represents the effect of up to ±10 cm displacement of the dosimeter compared to the reference source-to-dosimeter distance.

(iii) Due to time constraints, only limited features were tested on the angiographic systems. Only one x-ray protocol was tested and no measurement was performed in fluoroscopy mode because the dose rate would have been too low. Nevertheless it is expected that SDC accuracy is the same in fluoroscopy mode as in acquisition mode. The effect of the FOV, the table height, the source-to-image- detector distance, the field shape and the in-field collimation was not tested individually but investigated through clinical procedures. Their individual influence on the MSD calculation accuracy can therefore not be evaluated separately.

VII. Accuracy of the skin dose calculation software tools in real procedures

A. Introduction

In order to compare existing SDC software in real clinical procedures (i.e. performed on patients, not on phantoms), MSD were calculated with several SDC software for a large RDSR data base of three types of high-dose procedures.

B. Material

1. Procedures

RDSRs from 152 PCI (Percutaneous Coronary Intervention) procedures, collected in 7 angiographic rooms distributed over 3 hospitals. Those RDSRs are part of a larger data base collected within the activities of the VERIDIC project (Feghali J et al 2020). The detailed distribution of the procedures among the rooms and the angiographic systems is reported in Table 8. Only procedures for which the complete RDSRs were available were used.

2. Angiographic systems

The model of the angiographic systems from which RDSRs were collected are listed in Table 8.

Table 8: Angiographic systems (7), number of procedures available for MSD calculations and SDC software used

Participating site	Manufacturer	Model	Year	Number of procedures	SDC software used
A	Philips	Allura Clarity FD10 (2)	2008	22 & 27	DOSE, em.dose, OS, Radimetrics, SkinCare
B	Canon	Infinix 8000 D biplan	2017	31	DTS, em.dose, OS, SkinCare
C	GE	Innova 520 (2)	2014 & 2018	29 & 33	DOSE, em.dose, OS, RDM, SDM ICRP, SkinCare
C	Siemens	Axiom Artis Q Zen (2)	2013	6 & 5	DOSE, em.dose, OS, RDM, SkinCare

3. Skin dose calculation software tools

Skin dose estimates were performed with a total of 9 SDC software products, 8 of these products are presented above ((section Accuracy of the skin dose calculation software tools) DOSE, DTS, em.dose, OpenSkin, RDM, SDM ICRP and SkinCare. In addition, MSD estimates were obtained with Radimetrics, Bayer, Germany, for some procedures. Most software product were tested in default mode as presented earlier (*section Accuracy of the skin dose calculation software tools*). System-specific parameters were thus not input in the software tools if not available in the RDSR[6]; default values were used instead. The version of the SDC software solutions and the specific values of the user settings was presented earlier (Table 5). Different settings and version might have been used for the software products installed locally: DTS, Radimetrics and SDM. Details of the specific parameters used is unknown in these cases.

4. Statistical analysis

The arithmetic mean of the MSD estimates produced by different SDC software was calculated individually for each procedure. The mean MSD was used as a reference value for comparison purpose.

[6] Except for the online products which extract the calculation input from the modality.

The difference between the MSD estimated by a specific software product and the mean estimate was calculated for each procedure as in the following equation (3):

$$Diff_{soft\ X,P} = \frac{MSD_{soft\ X,P} - MSD_{mean,P}}{MSD_{mean,P}} \times 100\% \quad (3)$$

Where $MSD_{soft\ X,\ P}$ is the MSD estimate of a specific software product *X* for procedure *PI,* and $MSD_{mean,\ P}$ is the mean of all MSD estimates for procedure *P*. Descriptive statistics (mean, median, minimum, maximum, standard deviation and 95% coverage interval) of the difference were then computed for all procedures. Lin's concordance correlation coefficient (Lin L 1989), rho_{ccc}, was used to compare all the MSD estimates of a specific SDC software with the mean MSDs.

C. Results

Descriptive statistics, of the ratio between MSD estimate of a specific software solution and the mean MSD estimate over all software solutions are reported in Table 9. In general, the mean and the median of the difference $Diff_{soft\ X,\ P}$ did not differ strongly for a single software product. In addition, most software showed values closed to 0.

The absolute value of the minimum and maximum difference could be high and close, or exceed, 100% of the mean MSD estimate.

D. Discussion

From the 95% interval of the ratio between a specific MSD estimate and the mean estimate, it can be observed, most software produce MSD estimates relatively close to the mean MSD and, thus, relatively close to one another for the same procedure. In general, 95% of the MSD estimates were also within a limited range around the mean estimate (within ±40%), indicating that most software provides estimates in reasonable agreement to one another. Among the 5% of the remaining procedures, some MSD estimates could be far from the mean estimate for selected procedures, and thus differ strongly from other software estimates. These procedures resulting in discrepant MSD estimates are of particular interest for software developers.

Following McBride (2005) recommendations for interpretation, concordance between the MSD estimate of specific SDC software and the mean of the estimates was substantial for DOSE, em.dose, RDM and SkinCare. The concordance observed was moderate for DTS and SDM ICRP, and poor for OpenSkin and Radimetrics. It should be reminded that these guidelines, although frequently referred to, are subjective. Nonetheless, a clear difference can be observed between OpenSKin and Radimetrics and the rest of the software. Because of the limited number of MSD estimates produced using DTS and SDM ICRP, any conclusion relative to these software products should be viewed with caution. MSD estimate were computed for more than 100 procedures using DOSE, em.dose, OpenSkin and SkinCare, This number of data still seem insufficient to analyse the results of a specific software tool on a specific angiographic system.

Table 9: Descriptive statistics of the difference between MSD estimate of a specific software solution and mean MSD estimate over all software solutions and Lin's concordance correlation coefficient, rho_{ccc}

	RDM	SDM ICRP	SkinCare	OS	DOSE	em.dose	DTS	Radi-metrics
# procedures	71	26	151	151	121	118	25	74
mean (%)	4	10	0	1	0	1	-1	-3
median (%)	3	1	-2	3	1	-2	-1	-3
min (%)	-16	-23	-35	-94	-38	-33	-40	-43
max (%)	23	123	62	75	54	62	36	131
stdev (%)	8	27	15	23	16	17	18	24
95% interval %	[-10 ;20]	[-18 ;72]	[-23 ;43]	[-68 ;38]	[-29 ;41]	[-24 ;39]	[-37 ;35]	[-39 ;43]
rho_{ccc}	0.99	0.91	0.97	0.77	0.96	0.96	0.94	0.74

Since no measurements were performed, MSD calculations cannot be compared to reference measurements. Agreement between software is no conclusive evidence of accurate skin dose estimate, however, the trends observed are in general agreement with the results of the measurements following the acceptance protocol as reported in section Accuracy of the skin dose calculation software tools.

VIII. Conclusions

Acceptance and quality control (QC) testing protocols for the accuracy of SDC software in interventional cardiology were developed. Measurements following the newly developed Acceptance protocol were performed and used to assess the accuracy of 10 SDC software products in total.

The MSDs estimated by most SDC software products was within ±40% of the measurements and thus acceptable for routine use in clinical practice. The use of system specific settings for calculations of the MSD is implemented in all software but was not tested within the present project, as it might be the case in clinical practice. This has the potential to considerably increase the accuracy of the MSD monitoring.

The main limitation of the SDC software products is currently the lack of techniques for determining the patient body contour and position. This can dramatically degrade the software accuracy.

IX. Acknowledgments

The authors acknowledge Niki Fitousi (Dose), Claire Van Ngoc Ti (em.dose), Jonathan Cole (OpenSkin), Claire Steinville and Alain Christmann (SDM) and Marko Krajinović (SkinCare) for their help with the dose calculations.

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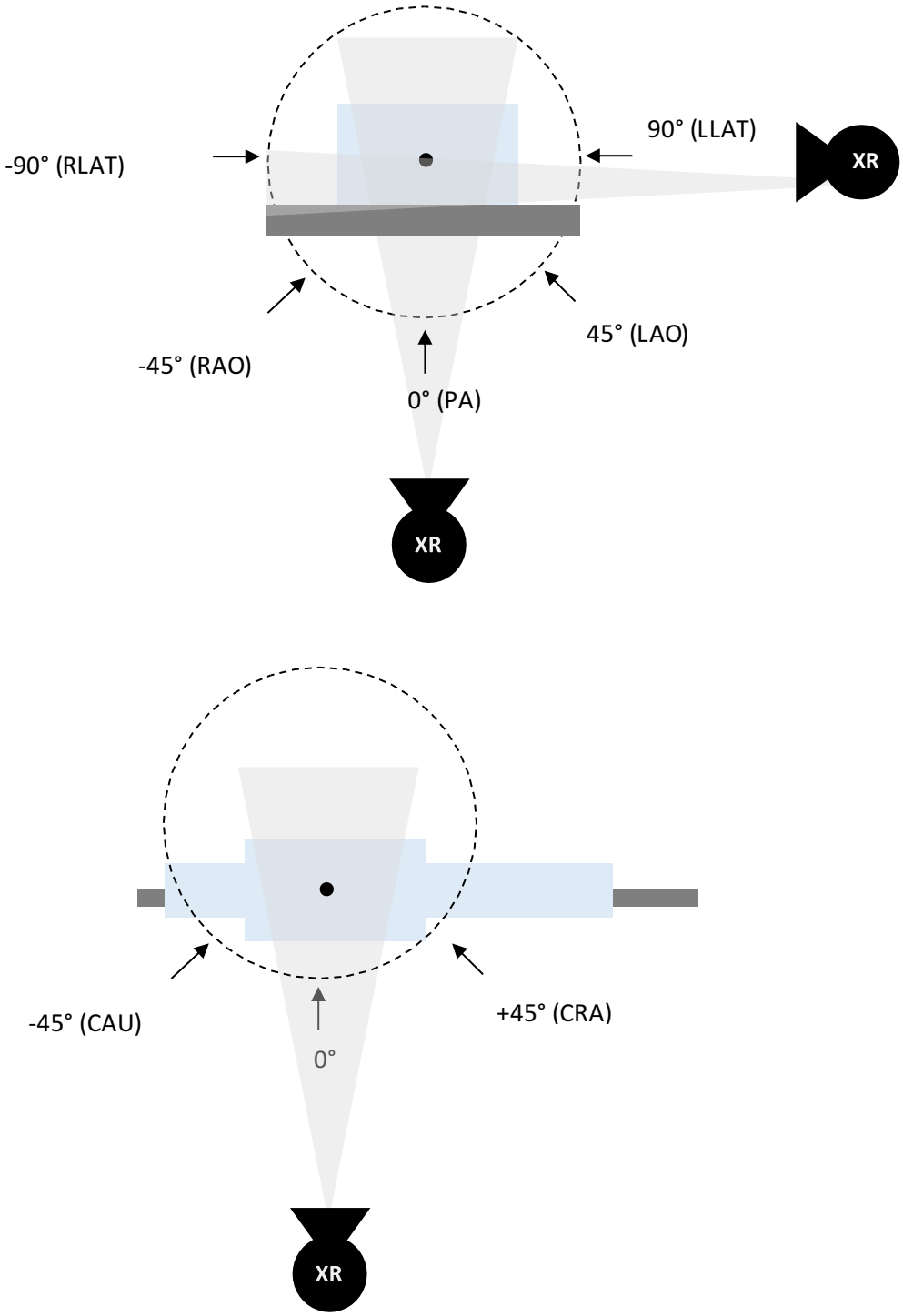
X. Annex 1: Beam angulation terminology



XI. Annex 2: clinical procedures

The following method was used to shorten real clinical procedures. Only a limited number of irradiation events were kept for each procedures so that those "shortened" procedures could be used as part of the Acceptance Protocol within a limited time frame. This method can easily be implemented in Excel.

1. Procedures with the highest cumulative $K_{a,r}$ were selected from the hospital archives.
2. Technical settings per irradiation event were extracted as an Excel file using a dose management software application connected to the PACS. Alternatively the data was extracted directly from the RDSRs using the Open source script developed in the frame of VERIDIC (available at XXX).
3. Fluoroscopy events were discarded because the – usually – low $K_{a,r}$ from this imaging mode makes it impractical for dose measurements when limited access is given to the angiography system.
4. Primary and secondary angles were rounded to multiple of 5°.
5. Irradiation events were then sorted according to the following parameters (named following the DICOM denomination) in the following order of importance: Rounded Positioner Primary Angle; Rounded Positioner Secondary Angle; Irradiation Event Type; Collimated Field Area; Table Height Position; Distance Source to Detector
6. Events were grouped according to the rounded angles, the Collimated Field Area, the Table Height Position and the Distance Source to Detector.
7. Only the groups contributing the most to the cumulative $K_{a,r}$ were kept. In the simplified procedures of the Acceptance protocol, it was decided to only keep 6 groups.
8. $K_{a,r}$ was summed up over each group and proportionally scaled so that the $K_{a,r}$ cumulated over all groups equal 1000 mGy.

XII. Annex 3: data collection template

Irradiation event	Measured value	Displayed/ calculated value	Deviation	Acceptability criterion	Pass? (Y/N)
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
CP1					
CP2					
CP3					

XIII. Annex 4: Dose maps

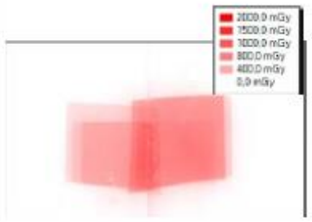
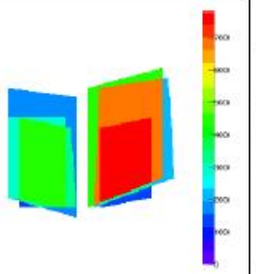
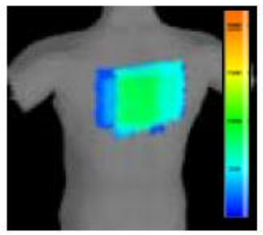
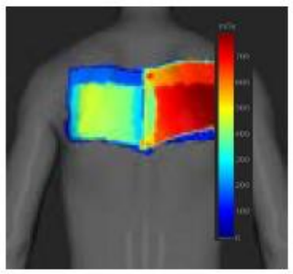
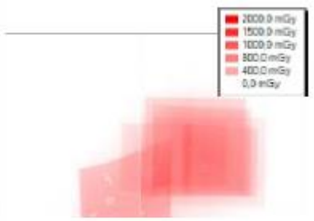
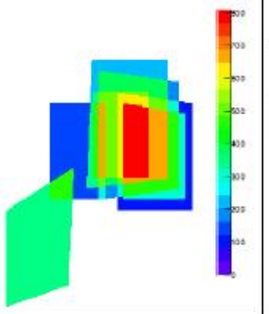
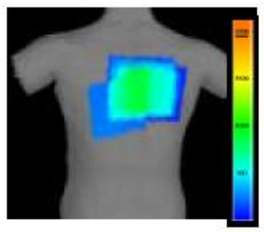
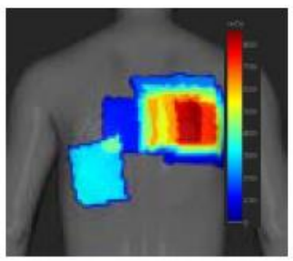
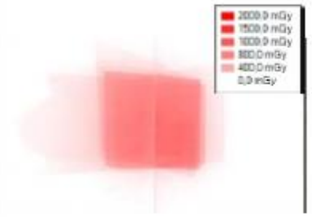
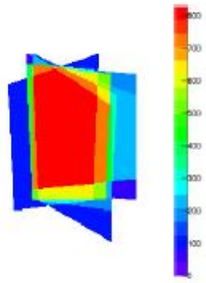
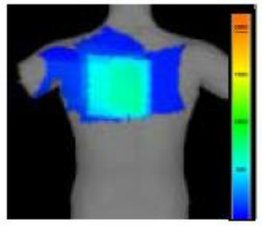
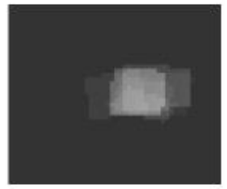
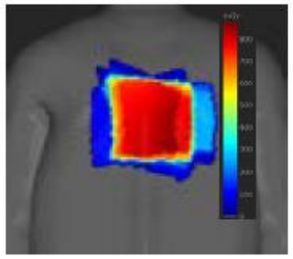
CP	Film	EM.dose	Modality (DTS)	OpenSkin	SkinCare
1					
2					
3					

Figure 13: Dose maps as measured with films on the back of a RA phantom for three clinical procedures using a Canon Infinix CF-i biplane system and as calculated with IDC. Patient's head points towards the top of the maps; patient's left is on the left side of the maps. Limited modifications of the dose maps (such as cropping or reorientation) as created by the SDC software were performed in order to facilitate a qualitative comparison.

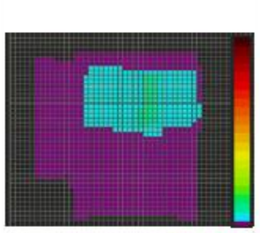
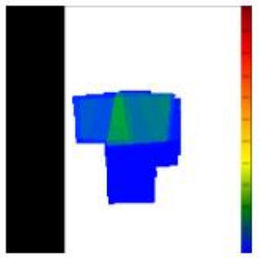
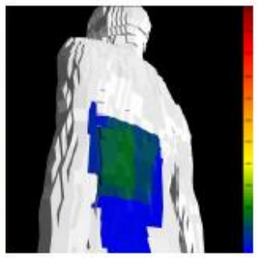
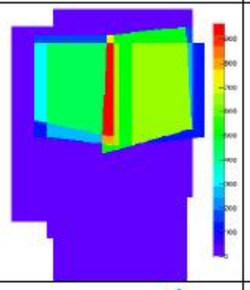
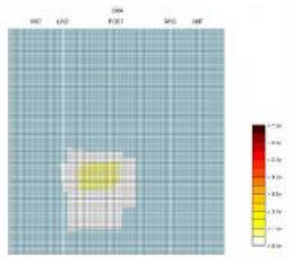
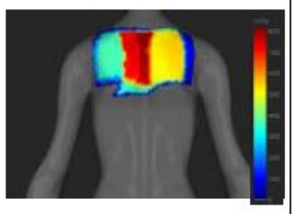
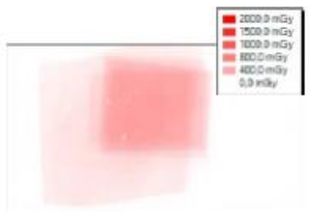
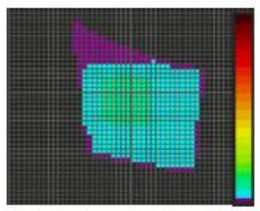
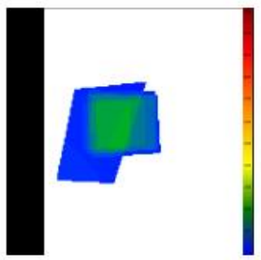
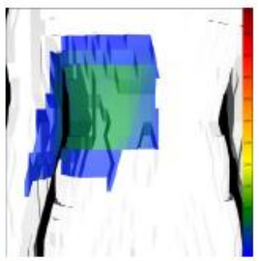
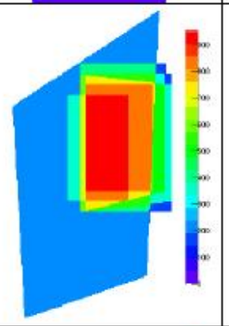
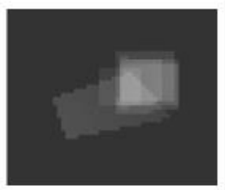
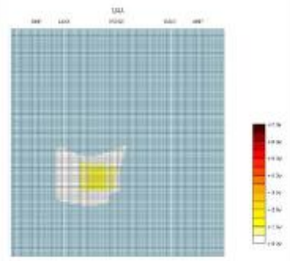
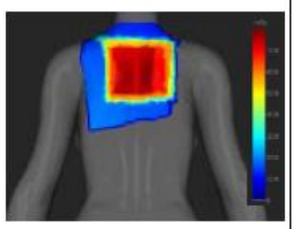
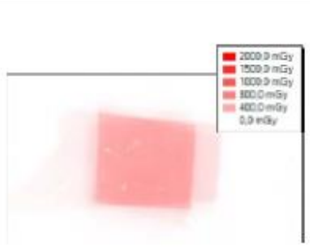
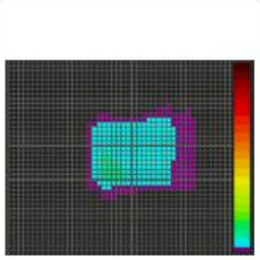
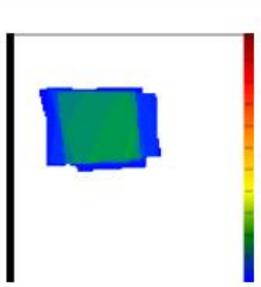
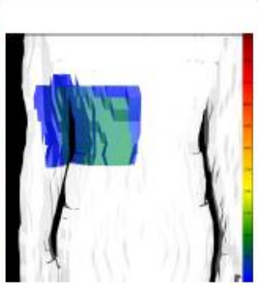
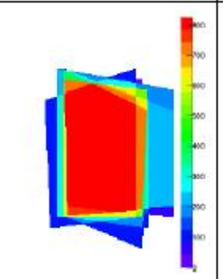
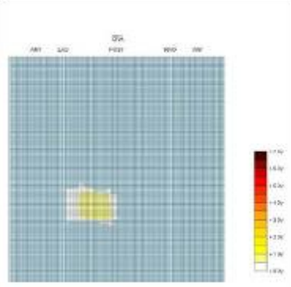
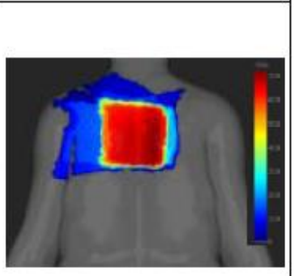
CP	Film	Dose	DoseWatch flat	DoseWatch ICRP	EM.dose	OpenSkin	RDM	SkinCare
1								
2								
3								

Figure 14: Dose maps as measured with films on the back of a RA phantom for three clinical procedures using a GE Innova IGS 540 system and as calculated with IDC. Patient's head points towards the top of the maps; patient's left is on the left side of the maps. Limited modifications of the dose maps (such as cropping or reorientation) as created by SDC software were performed in order to facilitate a qualitative comparison.

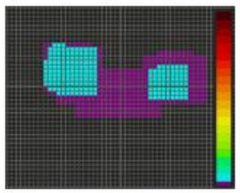
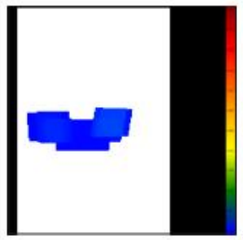
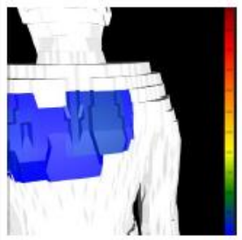
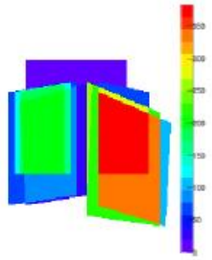
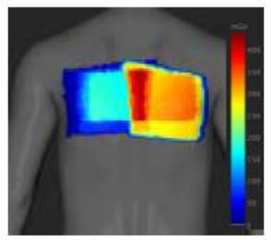
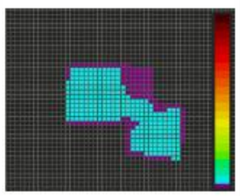
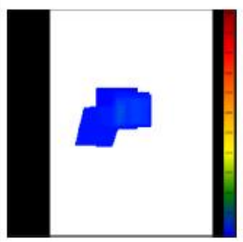
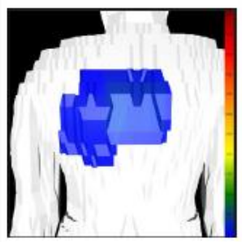
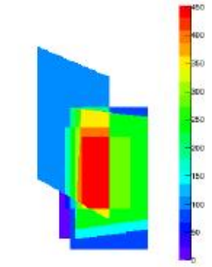
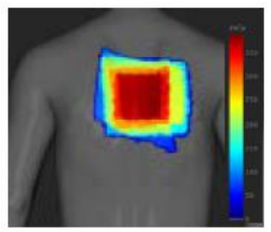
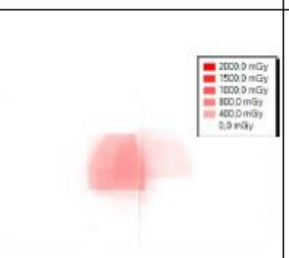
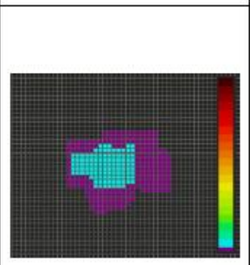
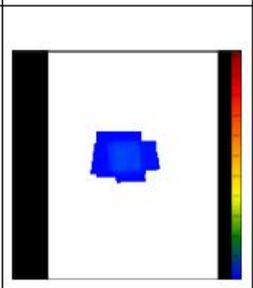
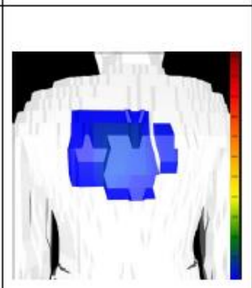
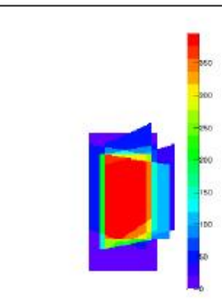
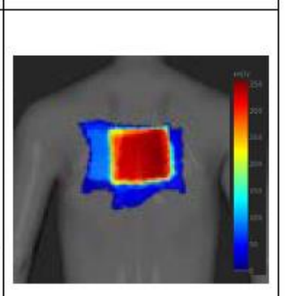
CP	Film	Dose	DoseWatch flat	DoseWatch ICRP	EM.dose	OpenSkin	SkinCare
1							
2							
3							

Figure 15: Dose maps as measured with films on the back of a RA phantom for three clinical procedures using a Philips Allura Xper system and as calculated with IDC software. Patient's head points towards the top of the maps; patient's left is on the left side of the maps. Limited modifications of the dose maps (such as cropping or reorientation) as created by SDC software were performed in order to facilitate a qualitative comparison.

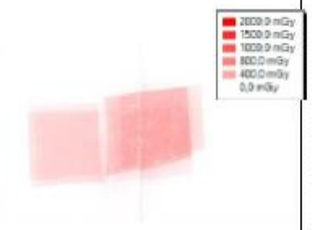
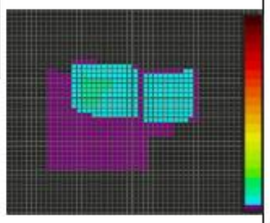
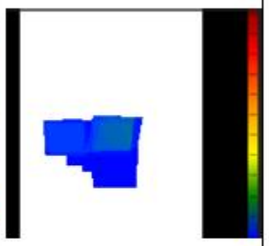
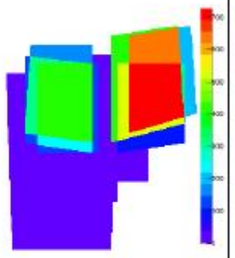
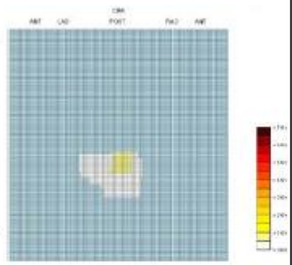
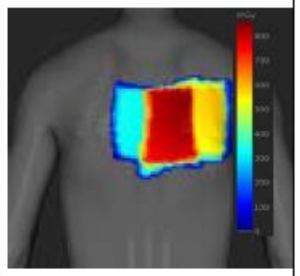
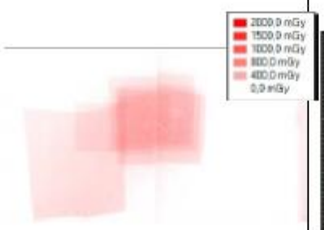
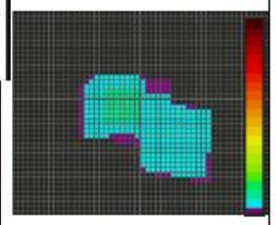
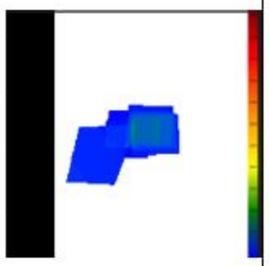
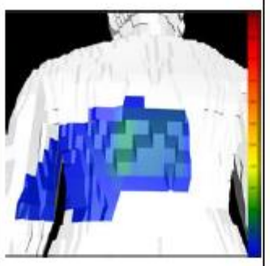
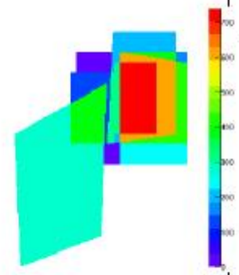
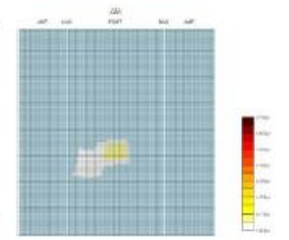
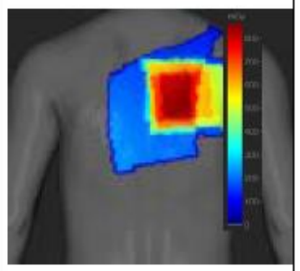
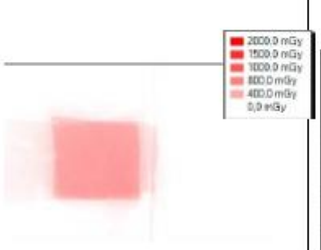
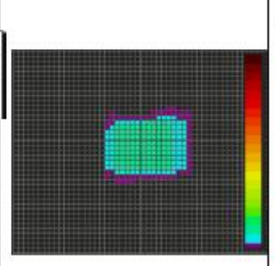
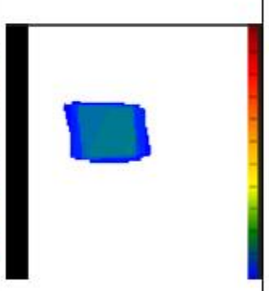
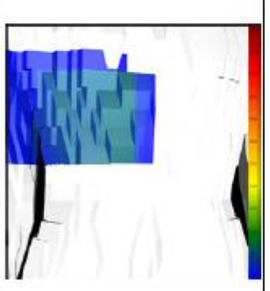
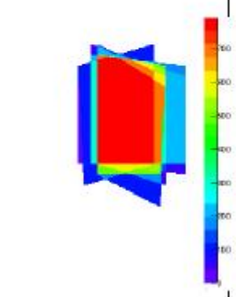
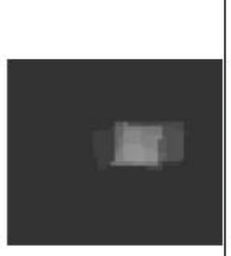
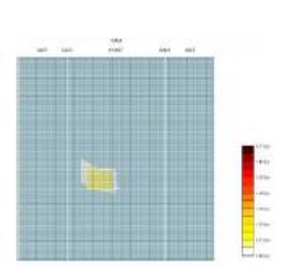
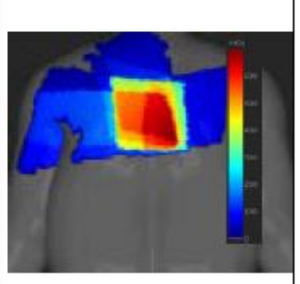
CP	Film	Dose	DoseWatch flat	DoseWatch ICRP	EM.dose	OpenSkin	RDM	SkinCare
1								
2								
3								

Figure 16: Dose maps as measured with films on the back of a RA phantom for three clinical procedures using a Siemens Artis Zee biplane system and as calculated with IDC. Patient's head points towards the top of the maps; patient's left is on the left side of the maps. Limited modifications of the dose maps (such as cropping or reorientation) as created by SDC software were performed in order to facilitate a qualitative comparison.

XIV. References

Alm-Carlsson G, et al (2007): Dosimetry in diagnostic radiology: an International code of practice Technical Reports Series no 457 (Vienna: International Atomic Energy Agency)

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