# TITLE: Accuracy of skin dose mapping in interventional cardiology: comparison of 10 software products following a common protocol

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## Abstract

*Purpose*: Online and offline software products can estimate the maximum skin dose (MSD) delivered to the patient during interventional cardiology procedures. The capabilities and accuracy of several skin dose mapping (SDM) software products were assessed on X-ray systems from the main manufacturers following a common protocol.

*Methods*: Skin dose was measured on four X-ray systems following a protocol composed of nine fundamental irradiation set-ups and three set-ups simulating short, clinical procedures. Dosimeters/multimeters with semiconductor-based detectors, radiochromic films and thermoluminescent dosimeters were used. Results were compared with up to eight of 10 SDM products, depending on their compatibility.

*Results*: The MSD estimates generally agreed with the measurements within ±40% for fundamental irradiation set-ups and simulated procedures. Only three SDM products provided estimates within ±40% for all tested configurations on at least one compatible X-ray system. No SDM product provided estimates within ±40% for all combinations of configurations and compatible systems. The accuracy of the MSD estimate for lateral irradiations was variable and could be poor (up to 66% underestimation). Most SDM products produced maps which qualitatively represented the dimensions, the shape and the relative position of the MSD region. Some products, however, missed the MSD region when situated at the intersection of multiple fields, which is of radiation protection concern.

*Conclusions*: It is very challenging to establish a common protocol for quality control (QC) and acceptance testing because not all information necessary for accurate MSD calculation is available or standardised in the radiation dose structured reports (RDSRs).

## Keywords

Interventional cardiology ; Skin dose ; Skin dose mapping; Quality Control Protocol

## Highlights

- Four interventional X-ray systems were tested with up to 8 skin dose mapping products
- SDM software can make considerable error in specific conditions
- No SDM product provided estimates within 40% for all set-ups and systems
- Few SDM products provided estimates within 40% for all set-ups on a specific system
- Establishing a common QC protocol for testing SDM products is currently unachievable



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## 1. Introduction

In interventional cardiology (IC), patients may be exposed to high doses to the skin resulting in tissue reactions following single or multiple procedures [1]. As the number and complexity of IC procedures have been steadily growing [2, 3], patient-specific dose calculation in IC has become a priority for European professional societies [4] and a European dosimetry network [5] over the years.
To address this issue, online and offline skin dose mapping (SDM) software products have been developed to estimate the skin dose delivered to the patient during IC procedures [6-11]. A recent review of the literature can be found in Malchair et al. [12]. Various studies have compared skin dose measurements with SDM software. Some studies included real clinical cases [11, 13-16] while others used physical phantoms [8, 10, 15, 17-19]. The dosimetric capabilities and accuracy of the SDM products could strongly differ depending on the irradiation settings and the interventional X-ray system tested. Those studies, however, were performed following different measurement protocols and/or for different patients, which makes comparison difficult. The protocols were also not intended to be used in clinical practice and could be challenging to perform on a regular basis. To date, no acceptance testing nor quality control (QC) protocols have been published for such products.
The European-funded project VERIDIC (Validation and Estimation of Radiation skIn Dose in Interventional Cardiology) aimed to contribute to the harmonisation of radiation dose structured reports (RDSRs) and the validation of SDM software products in interventional cardiology. Three work packages were created to (i) review the existing SDM products and identify the need for RDSR standardisation, (ii) contribute to the development of a protocol for testing the accuracy and the performance of the SDM software products and (iii) investigate the determinants of high skin doses. Links to the project results are available on the project web page [20].
This article reports the results of the second work package of the VERIDIC project. In particular, the results of the measurements performed on four interventional X-ray systems following a common protocol are presented and a comparison with the calculated maximum skin dose (MSD) for up to 10 SDM products is made. Protocol requirements for developing acceptance testing and QC protocols for SDM products useable in clinical practice, are discussed and a summary of the limitations are given. Acceptability criteria are also discussed.



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## 2. Material

### 2.1. Interventional X-ray systems

Measurements were performed on one interventional X-ray system from the four major manufacturers: a Canon Infinix CF-I biplane (Canon Medical Systems, Japan), a General Electric (GE) Innova IGS 540 (GE Healthcare, United States of America (USA)), a Philips Allura Xper (Philips Healthcare, the Netherlands) and a Siemens Artis Zee biplane (Siemens Healthineers, Germany). All were equipped with flat panel detectors. Details of the systems are given in Table 1. The Canon system was installed in Switzerland, the GE system in France and the Philips and Siemens systems in Belgium. All systems passed the respective national regulatory QC assessment. Only the main X-ray tube was tested on biplane systems.

*Table 1: interventional X-ray system characteristics*

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

*[1] reported field of view (FOV) values are values are measured on the diagonal for Philips and Siemens systems, and measured horizontally and vertically for Canon and General Electric systems ; [2] only main tube tested.*

### 2.2. Measurement protocol

The protocol was developed to serve as a basis for an acceptance testing protocol and, therefore, was intended to be performed within a limited timeframe and with material and equipment readily available to medical physicists. It is composed of nine fundamental irradiation set-ups, and three combinations of set-ups which simulate short clinical procedures and are relatively fast to perform. In addition, four preliminary measurements were made to evaluate the calibration of the air kerma at the reference point ($K_{a,r}$) and the table and mattress transmission properties of the tested X-ray systems.
The detailed protocol and how it can be applied to other SDM software products and interventional X-ray system is available in the supplementary material.

#### $K_{a,r}$ calibration and table and mattress transmission

The $K_{a,r}$ accuracy and the transmission factors were evaluated at both low (about 80 kVp) and high tube voltage (about 120 kVp). Radiopaque material was positioned close to the flat panel detector to reach



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the desired tube potential. The dosimeters were positioned in the primary beam at the interventional reference point (isocentre minus 15 cm). The irradiation were first performed with the dosimeters in air (i.e. located on an extruded polystyrene foam panel in the primary beam and the table outside then with the dosimeters on top of the table and the mattress in the primary beam.
The $K_{a,r}$ accuracy was calculated as the ratio of the $K_{a,r}$ as available in the RDSR and as measured. The table and mattress transmission factors were calculated as the ratios of the $K_{a,r}$ measured in air and on the top of the table and mattress.

**Fundamental irradiation set-ups**

The fundamental irradiation set-ups consist of simple irradiations on a phantom using between one and three beam projections. Those set-ups were chosen to verify that key parameters which can significantly affect the skin dose and in particular the MSD, were appropriately taken into account by SDM software. Different patient thicknesses and combinations of up to three overlapping X-ray projections were investigated individually.
The main settings of the fundamental irradiation set-ups are detailed in Table 2. When these settings were unavailable on a specific interventional X-ray system, the closest available settings were selected. The irradiations were all performed using the clinical cardiology protocol most commonly used on the system tested and in acquisition mode with the highest image frame rates (15 or 30 frame per second (fps)). The X-ray source to image detector distance (SID) was set to 100 cm or as close as possible to this value. A field of view (FOV) of 20 cm or as close as possible to this value, as displayed on the console, was used. Displayed FOV values are measured on the diagonal for Philips and Siemens systems, and measured horizontally and vertically for Canon and GE systems. No in-field collimation was used. The tube voltage and the added filtration were set automatically by the system.
For set-up 1 to 6, Polymethylmethacrylate (PMMA) plates (up to 6 plates of 5 cm thickness each, 30 x 30 cm² surface) were used to build phantoms of various thickness (10, 15, 20, 25 and 30 cm), representing paediatric or small adult patients up to a large adult patient. A male, adult Rando Alderson (RA) phantom [21], which is a 1.70 m tall and 75 kg anthropomorphic phantom composed of tissue equivalent material, was used to investigate the effect of beam angulations on a more realistic patient representation (set-ups 7 to 9).
The dosimeters were positioned in the primary beam at the interventional reference point, except for set-up 9, which is a strictly lateral projection. When a phantom was used, the dosimeters were positioned on the mattress under a jig made of an extruded polystyrene foam panel with a specific recess to host the dosimeters ; the phantom was subsequently positioned on top of the jig (Figure 1). For set-up 9, the dosimeters were simply taped on the phantom side. Doses of at least a few hundred mGy were achieved at the dosimeters to obtain doses sufficient for accurate dosimeter reading and skin dose calculation. The RDSR of each radiation set-up was registered individually for the skin dose calculations using SDM software.

*Table 2: Measurement protocol: Fundamental irradiation set-ups*

| Irradiation set-up | Purpose of measurement | Configuration | Projections* | Tube potential |
|---|---|---|---|---|
| **1** | Effect of phantom thickness | Phantom 20 cm + mattress + table | PA | Automatic selection |



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| | | | | |
|---|---|---|---|---|
| **2** | Effect of phantom thickness | Phantom 25 cm + mattress + table | PA | Automatic selection |
| **3** | Effect of phantom thickness | Phantom 30 cm + mattress + table | PA | Automatic selection |
| **4** | Effect of phantom thickness | Phantom 15 cm + mattress + table | PA | Automatic selection |
| **5** | Effect of phantom thickness | Phantom 10 cm + mattress + table | PA | Automatic selection |
| **6** | Effect of field overlap | RA Phantom + mattress + table | PA | Automatic selection |
| **7** | Effect of field overlap | RA Phantom + mattress + table | PA + LAO 20 | Automatic selection |
| **8** | Effect of field overlap | RA Phantom + mattress + table | PA + LAO 20 + PA CRAN 15 | Automatic selection |
| **9** | Effect of lateral irradiations | RA Phantom + mattress + table | LLAT or RLAT | Automatic selection |

*PA-posterior anterior, LAO-left anterior oblique, LLAT-left lateral, RLAT-right lateral, CRAN-cranial



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**Simulated procedures**

Only limited values of the key parameters influencing the skin dose calculations were tested in the fundamental set-ups. There are many other parameters affecting the skin dose (for example, the field size) which cannot be tested in the limited time available to the medical physicists in clinical practice. Therefore, three short procedures were performed to simulate more realistic conditions. Those short procedures are simply referred to as simulated procedures in the rest of the article. Each of those clinical procedure consists of a combination of six irradiation settings derived from actual high doses procedures selected from a set of percutaneous coronary interventions collected in 12 European hospitals [22]. Procedure parameters were adapted to the capabilities of the interventional X-ray system tested by using the closest parameters available.

The irradiations were all performed using the most commonly used clinical cardiology protocol in – cine – acquisition mode with high image frame rate (15 or 30 fps). Each procedure cumulated a $K_{a,r}$ of 1000 mGy. The patient table height, the SID, the FOV and the angular position of the tube (primary and secondary angles) were set individually for each of the six set-ups included in each procedure. The tube voltage and the added filtration were set automatically by the X-ray system. Details of the simulated procedure settings can be found in Section II.C.2 and table 2 of the supplementary material.

The dosimeters were positioned as per the fundamental irradiation set-ups. An adult RA phantom, was used for all measurements. The RDSR of each procedure (covering 6 set-ups) was registered individually for the skin dose calculations with the SDM products.

### 2.3. Skin dose mapping software tools

Skin dose estimates were performed with 10 SDM software products: CAATSDOSE (Centre d'Assurance de qualité des Applications Technologiques dans le domaine de la Santé, France); CareMonitor (Siemens Healthineers, Germany); DOSE by Qaelum (Qaelum, Belgium; referred to as DOSE in the rest of this document); DoseMap (GE Healthcare Systems, France); Dose Tracking System (Canon Medical Systems, USA; referred to as DTS in the rest of this document); em.dose (Esprimed, France); OpenSkin (J. Cole, open-source [23]); Radiation Dose Monitor (RDM) (Medsquare, France); DoseWatch Skin Dose Map (GE Healthcare Systems, France; referred to as DWSDM in the rest of this document), and SkinCare (University of Belgrade, Serbia). References to one relevant publication for each product is listed in Table 3. CareMonitor, DOSE, DoseMap, DTS, em.dose, RDM and DWSDM are commercial products incorporated in the interventional X-ray system or as a module in dose management software; while CAATSDOSE is an Excel calculation sheet, SkinCare is academic research software and OpenSkin is an Open-source set of Python scripts. Although CareMonitor calculates the maximum accumulated $K_{a,r}$ and, thus, does not account for the table and mattress attenuation nor the radiations scattered by the patient, it was included in the study.

The version of the SDM software products and the specific values of the main calculation parameters, including user-customisable settings, are presented in Table 3. The $K_{a,r}$ accuracy and the table transmission factor as measured on the systems were used for the calculations if the SDM product allowed those parameters to be readily customised. In practice, the average table and mattress transmission factor as measured at two tube voltages was used; however, for those SDM products only allowing the table equivalent Al thickness as input, default values were used. For all other parameters, system-specific parameters were used as input for skin dose calculations if the SDM products could extract them from the RDSR or the modality. Otherwise, default values were used. These default values can differ from the values set on similar SDM software across sites.



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An extended description of the software products, their capabilities and the calculation settings are available in the first deliverable of the present project [12]. Two versions of DWSDM were used: a commercial version implementing the International Commission on Radiological Protection (ICRP) voxel phantom (referred to as DWSDM ICRP in the rest of this document) and a research version implementing a flat phantom (referred to as DWSDM flat in the rest of this document). Results of both software products are presented separately.

RDSRs were extracted in the .dcm format after each irradiation set-up and after each simulated procedure to be used as input for offline SDM 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 SDM products could be combined with the four interventional X-ray systems used for the measurements, mainly due to compatibility issues. The interventional X-ray systems tested with each software product is reported in Table 3. CAATSDOSE, em.dose and OpenSkin were specially modified for the present project in order to allow skin dose estimates for Philips and Canon interventional X-ray systems. DTS and DoseMap were the only products which could display both the MSD and the dose map online. All software but CareMonitor produced a map of the skin dose distribution; however the maps produced by DoseMap could not be retrieved due to a faulty manipulation at the time.



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*Table 3: Characteristics of the skin dose mapping software products and specific values of the user settings used for the MSD calculations*

| **Name** | **Manufacturer/ Developer** | **Version (*original reference*)** | **User customisable settings** | **Patient model** | **Tested with** | **Comments** |
|---|---|---|---|---|---|---|
| **CAATSDOSE** | CAATS | 2015 (personal communication) | - $K_{a,r}$ correction factors[1]<br>- Mattress thickness = 4 cm<br>- Distance table to head = 10 cm<br>- Table/mattress transmission[2] | Flat | Canon, GE, Philips, Siemens | - Compatible with all vendors<br>- Excel sheet |
| **CareMonitor** | Siemens | Unknown | Unknown | Unknown | Siemens | - Vendor-dependent<br>- Online product |
| **DOSE by Qaelum (DOSE)** | Qaelum | 19.11 *(Hintenlang et al 2018 [24])* | -<br>- $K_{a,r}$ correction factor[1]<br>- Mattress thickness =4 cm<br>- Table equivalent thickness = 1.65 mmAl | Scalable elliptical phantom | GE, Philips, Siemens | - Compatible with all vendors |
| **DoseMap** | GE | Innova IGS 540 M4017064 *(Bordier et al 2015 [10])* | - Adult local dose threshold = 2 Gy<br>- Mattress thickness = 5 cm | Scalable elliptical phantom "single model" | GE | - Vendor-dependent<br>- Online product |
| **Dose-Tracking System (DTS)** | Canon | V6.35 *(Bednarek et al 2011 [8])* | - Patient model | Caeser voxel phantom (under 84 kg model) | Canon | - Vendor-dependent<br>- Online product |
| **DoseWatch Skin Dose Map (DWSDM flat)** | GE | Versions 3.1.2 *(Gardavaud et al 2018 [25])* | - $K_{a,r}$ correction factors[1]<br>- Mattress thickness = 4 cm<br>- Table equivalent thickness = 0.14 mmAl<br>- Distance table to head = 10 cm | Flat | GE, Philips, Siemens | - Compatible with all vendors |
| **DoseWatch Skin Dose Map** | GE | Versions 3.1.2 | -- $K_{a,r}$ correction factors[1]<br>- Mattress thickness = 4 cm<br>- Table equivalent thickness = 0.14 mmAl | ICRP voxel phantom | GE, Philips, Siemens | - Compatible with all vendors |



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| | | | | | | |
|---|---|---|---|---|---|---|
| **(DWSDM ICRP)** | | *(Gardavaud et al 2018 [25])* | - Distance table to head = 10 cm | | | |
| **em.dose** | Esprimed | Unknown *(Greffier et al 2017 [14])* | - Patient model<br>- $K_{a,r}$ correction factor[1]<br>- Table/mattress transmission[2]<br>- Table and mattress thickness =2.5 cm | Flat | Canon, GE, Philips, Siemens | - Compatible with all vendors<br>- Code modified to handle Canon and Philips systems |
| **OpenSkin** | Cole J. | - | - Patient model<br>- $K_{a,r}$ correction factor[1]<br>- Mattress thickness = 0 cm<br>- Table thickness = 2 cm | Flat | Canon, GE, Philips, Siemens | - Compatible with all vendors<br>- Code modified to handle Canon and Philips systems |
| **Radiation Dose Monitor (RDM)** | Medsquare | 1.4.4 *(Habib Geryes et al 2018 [17])* | - Patient model<br>- $K_{a,r}$ correction factor[1]<br>- Table/mattress transmission[2]<br>- Mattress thickness = 2 cm<br>- Table thickness = 0.5 cm | Flat | GE, Siemens | - Compatible with all vendors but Canon |
| **SkinCare** | University of Belgrade | *(Krajinovic et al 2020 [11])* | - $K_{a,r}$ correction factor[1]<br>- Table/mattress transmission[2] | Anthropomorphic voxel phantom | Canon, GE, Philips, Siemens | - Compatible with all vendors |

*[1]$K_{a,r}$ correction factor values averaged over measurements at two tube potentials were input: 0.98, 0.92, 0.90 and 0.90 were used for Canon, General Electric (GE), Philips and Siemens systems, respectively.*

*[2]table and mattress transmission factor values derived from measurements were used: 20%, 30%, 10% and 30% were used for Canon, GE, Philips and Siemens systems, respectively*



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### 2.4. Dosimeters

Three types of dosimeters were used: Thermoluminescent dosimeters (TLD), radiochromic films and dosimeters/multimeters with semiconductor-based detectors used routinely for QC measurements (referred to as QC dosimeters in the present work). QC dosimeters were used as reference for assessing the accuracy of the $K_{a,r}$ displayed by the interventional X-ray systems and the table and mattress transmission effects. TLDs were used to estimate the accuracy of the SDM software tools when different phantom thicknesses were used (set-ups 1 to 6 and 9) and when a limited number of overlapping projections were used (set-ups 7 and 8). Films were used to produce dose maps of the three simulated procedures.

Three models of QC dosimeters were used for the measurements. An X2 solo and a X2 (both from Raysafe, Sweden) were used for the measurements on the GE and the Canon systems, respectively. An Accu-Gold (Radcal, USA) was used for the measurements on the Philips and GE systems. All three QC dosimeters were calibrated using a RQR-8 reference beam at Commissariat à l'énergie atomique et aux énergies alternatives (CEA) primary standard laboratory. Their energy response was also characterised for beam qualities representative of IC procedures [26]. 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).

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 out 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 a RQR-8 reference beam [27] at CEA primary standard laboratory. The expanded uncertainty (k=2; 95% confidence interval) was 16%, taking into consideration the standard uncertainties (k=1) associated with the energy dependence (5%) and the angular dependence (4%) [26], 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%)),.

One 25.4 x 30.48 cm² XR-RV3 Gafchromic films (Ashland, USA) was used for each clinical procedure. The uncertainty was calculated following the scenarios suggested by Farah et al [28]. Typical uncertainties in film measurement ranged from 5% to 40% (k=1) [28], depending on the calibration and reading scenarios. Three scenarios exist. Scenario A is related to the tightly controlled measurement conditions, adequate laboratory calibrations and well-defined readout protocol. Scenario B also describes the case where a well-defined laboratory calibration is performed while other influencing parameters related to clinical application of dosimetry films are less controlled. Finally, Scenario C describes the worst case scenario where the conditions of exposure, film handling and readout were weakly controlled and where corrections for the relevant influence quantities were not made. For all different steps except uncertainties related to film, scenario A was used as the dose delivery was done in a primary calibration laboratory (Laboratoire National Henri Becquerel), and the methodology was followed closely with sufficient 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 and most importantly they were sent through postal services. The uncertainty description



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and its estimate are provided in the supplementary material. Based on this uncertainty calculation, the expanded standard uncertainty (k=2; 95% confidence interval) was 26% for film measurements.



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### 2.5. Deviation of the measured MSD

For irradiation set-ups 1 to 9 and during the simulated procedures, the ratio of the calculated and the measured MSD values was calculated as:

$$ratio(\%) = \left(\frac{D_{calc}}{K_{a,e} \times f_{air,water}}\right) \times 100\ \% \qquad \textit{Equation 1}$$

And the deviation between the calculated and the measured MSD values was calculated as:

$$deviation(\%) = (100\% - ratio(\%)) \qquad \textit{Equation 2}$$

Where $D_{calc}$ is the MSD calculated by the SDM software, $K_{a,e}$ is the entrance surface air kerma as measured by the dosimeter and $f_{air,water}$ is the ratio of mass energy-absorption coefficients. A single value of 1.06 was used as it limits the uncertainty for the energies encountered in IC as reported by Benmakhlouf [29]. No acceptability criteria currently exist for SDM accuracy. A 40% deviation range was used for the purpose of the result analysis. This range is suggested based on a 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 $K_{a,r}$. Because no recommendation on the maximum acceptable deviation for the $K_{a,r}$ value is made in the European Commission guidelines [30], the limit set for the $P_{KA}$ (35%) was used instead.

## 3. Results

### 3.1. $K_{a,r}$ calibration and table and mattress transmission

The results of the displayed $K_{a,r}$ accuracy are reported in Table 4. For all the systems tested, the accuracy of the displayed $K_{a,r}$ without table or mattress in the X-ray beam 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 except on the Canon system at high tube voltages. When the table and the mattress were in the X-ray beam, 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. These results correspond to table and mattress transmission factors ranging from 54% to 89% at low tube voltage and from 69% to 90% at high tube voltage.

*Table 4: Accuracy measurements of the displayed $K_{a,r}$ values and transmission factor (reported in parenthesis).*

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

### 3.2. Fundamental irradiation set-ups

*PMMA slab phantom (set-ups 1 to 5)*



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The ratio of the calculated and the measured MSD values for PMMA phantom thicknesses ranging from 10 to 30 cm are reported in Figure 2 to Figure 5 for Canon, GE, Philips and Siemens systems, respectively. The tube voltage and half-value layer (HVL) values of the irradiations are reported in the same figures.

Among all SDM products, only SkinCare provided MSD estimates within ±40% of the measurements for all phantom thicknesses on the tested systems. Some products, however, provided results within 40% of the measurements for all tested systems but significantly overestimated the MSD for 10 and 15 cm PMMA thicknesses on the Siemens system only. They are em.Dose (tested with all four interventional X-ray systems); DWSDM flat and ICRP (GE, Philips and Siemens) and RDM (GE and Siemens systems). Results from CAATSDOSE and OpenSkin (all four systems); and CareMonitor, DoseMap and DTS (on Siemens, GE and Canon systems only, respectively) were less consistent and could exceed 40% even for thicknesses between 20 and 25 cm, which would cover numerous IC patients. Some SDM products also provided MSD estimates within ±20% for all phantom thicknesses on a specific system (e.g. DOSE, em.Dose, RDM, DWSDM flat and ICRP and SkinCare on the GE system). The coefficients of variation (COVs) of the MSD estimates for a specific phantom thickness was relatively small for Philips (16% to 19%) and GE (12% to 21%), which indicates that most software provided comparable estimates. COV ranges could be higher for the Siemens system (16% to 25%), mainly because of some outlying values for irradiations of small PMMA thicknesses. The COV ranges were larger for the Canon system (19% to 34%). This was mostly due to DTS outlying values.



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*Rando Alderson phantom (set-ups 6 to 9)*

The ratio of the calculated and the measured MSD values for the fundamental irradiation set-ups on the RA phantom (set-ups 6 to 9) are reported in Figure 6 to Figure 9 for Canon, GE, Philips and Siemens systems, respectively.
Only three SDM products provided MSD estimates within 40% for all RA phantom irradiations on the tested systems: SkinCare (on all four interventional X-ray systems), DOSE (GE, Philips and Siemens) and DoseMap (on the GE system). Three software products (em.dose, OpenSkin and DWSDM flat) could not provide MSD estimates for lateral irradiations. Excluding the lateral irradiation (event 9), all SDM products with the exception of CAATSDOSE on the Philips system provided MSD estimates within 40% on all four tested X-ray systems. Some SDM products could provide MSD estimates within ±20% for all the irradiation configurations but the strictly lateral projection (set-ups 6 to 8) on a specific system, e.g. estimates from em.Dose, SDM flat and ICRP and SkinCare on the Philips system.
The COV ranges on the RA phantom (excluding the lateral irradiations) was small for the GE and Siemens systems (15% to 16%, and 9% to 10%, respectively). The COV ranges were larger for the Canon system (8 to 30%) and Philips systems (16% to 25%).

### 3.2. Simulated procedures

*Maximum skin dose accuracy*

The ratio of the calculated and the measured MSD values for three simulated procedures on the RA phantom are reported in Figure 6 to Figure 9 for Canon, GE, Philips and Siemens systems, respectively.
Five SDM products provided MSD estimates within ±40% for the three simulated procedures on the tested systems: OpenSkin (on all four interventional X-ray systems), SDM flat and ICRP (GE, Philips and Siemens), RDM (on GE and Siemens) and DoseMap (on the GE system). Results of the remaining software products showed more variability: em.Dose and SkinCare were within ±40% for all four systems but the Philips one; CAATSDOSE was within ±40% for the Canon and GE systems only; and DOSE exceeded ±40% for at least one simulated procedure on each tested system (GE, Philips and Siemens).
The variability of the MSD estimates among the SDM software product for a specific procedure on a specific system was usually smaller or equal to the variability of fundamental irradiation configurations on the PMMA and RA phantoms (set-ups 1 to 5 and 6 to 9, respectively). Across the three procedures, the COV ranged from 7% to 13%, 14% to 20%, 17% to 18% and 11% on the Canon, GE, Philips and Siemens systems, respectively.

*Dose map accuracy*

The dose maps measured with the gafchromic films, as well as those produced by the SDM software tools are reported in Figure 10 to Figure 13. Again, it should be noted that those maps were produced with the settings of the SDM products at the time of the calculations and may not be representative of the values set on similar SDM software available in other sites. Colour choice was relatively uniform. Warmer colours were used to indicate higher doses, except for OpenSkin which presented doses in various shades of grey (the colour scales could not be used). 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 dynamically adapted to the magnitude of the displayed MSD on maps from DOSE, DWSDM, DTS, OpenSkin and RDM.



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The different patient representations, colour scales and resolutions made comparison challenging. Limited modifications (such as cropping or reorientation) of the dose maps as created by SDM software were therefore performed in order to facilitate a qualitative comparison. From a qualitative, visual comparison, it appears that all maps reproduced the dimensions and the relative position of the region of the MSD on the GE and Siemens systems accurately. An exception was CAATSDOSE and 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 estimated shape and size did not represent the measurements, 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 first two procedures on the Canon system, most software products missed the position of the MSD region which was situated at the intersection of overlapping fields. In contrast, the results were better for the last procedure.

## 4. Discussion

### 4.1. Free in air and on table and mattress measurements

The first measurements made free in air and on the table and mattress confirmed that the $K_{a,r}$ of all systems was within the accuracy limits of the respective national regulations (on $P_{KA}$ in the case of Switzerland). Since the calculated MSD is directly proportional to the displayed $K_{a,r}$, the accuracy of the $K_{a,r}$ is crucial information for MSD estimates [12]. The considerable spread of transmission factors among interventional X-ray systems is not new (e.g., [31]) and this stresses the importance of using measured transmission values rather than default values in order to further improve the accuracy of the MSD estimates. The table transmission characteristics are also worth considering when comparing dose indicators such as $K_{a,r}$ or $P_{KA}$ values from different systems.

### 4.2. On phantom measurements

MSDs were measured on PMMA slab phantoms of five different thicknesses (irradiation set-ups 1 to 5) and a RA phantom exposed with four beam angulations (irradiation set-ups 6 to 9) during three simulated procedures. MSD estimates were then calculated, using at least four SDM tools on Philips and Canon X-ray systems, up to eight on GE and Siemens systems. From discussions with the software developers, this greater software compatibility with GE and Siemens systems is related to the fact that GE and Siemens define the table height with respect to the system isocentre [32]. 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 X-ray-source-to-table-top distance accurately. This can lead to systematic errors.

*PMMA slab phantom (set-ups 1 to 5)*

On the Siemens system, there was a clear improvement in the MSD estimates from all SDM products when the PMMA phantom thickness increased. This may be due to an overestimation of the phantom thickness and thus the backscatter factors (BSFs) for the thinner phantom thickness. This assumption could be further strengthened by the transmission on the Siemens system varying considerably for lower kVp/HVL while most SDM products use a single table transmission value for all beam qualities. CareMonitor estimates were within 40% of the measured doses for PMMA thicknesses higher than 20 cm, although that software product only provides an estimate of the



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maximum cumulative $K_{a,r}$. The rather good agreement between the maximum cumulative $K_{a,r}$ and the MSD for the thicker PMMA phantoms might be due, in part, to the fact that the table/mattress transmission and the BSFs increase with the phantom thickness (and the beam quality). Indeed, for the smallest PMMA phantom thicknesses, the table transmission and the BSFs are low and the displayed $K_{a,r}$ thus strongly overestimated the measured MSD. For greater phantom thicknesses, the BSF and the table transmission were higher and the $K_{a,r}$ was thus closer to the MSD.
On the Philips system, no clear effect of the varying PMMA thickness could be observed. The MSD estimates (except estimates from OpenSkin) remained nearly constant irrespective of the phantom thickness. This trend could be partly explained by the dependence of the table and mattress transmission factors as function of the tube voltage and the additional filtration. A single thickness value was used by the SDM products. For the Philips system, no significant variation of the transmission factor was measured (Table 2), while for the Siemens system there was a noticeable increase (54% to 69%). On the GE and the Canon systems, no clear trend could be observed with respect to the PMMA thickness, considering the measurement uncertainty. The poor results of the manufacturer-specific SDM products (DTS and DoseMap) for specific phantom thickness was unexpected for these two systems. This is probably due to incorrect patient representation, which lead to use of an incorrect BSF. Indeed, the phantom model representing the patient can be manually selected from a list (optional on DTS) or calculated from patient's height and weight (DoseMap and optional on DTS). The height and weight used for the patient registration as proposed in the protocol might therefore have caused inadequate phantom modelling by the SDM tools. This selection process appears to be a major shortcoming, particularly when a PMMA phantom is used. Ideally, developers should implement methods to accurately determine the patient contour; in the meanwhile, implementing PMMA slab phantom models in their software tools, would be an efficient solution. In addition, to the authors' knowledge, DTS is calibrated only with a 20 cm PMMA phantom on site as presented in [8], which can further explain some discrepancies.
When considering the MSD estimates of a specific SDM product on multiple interventional X-ray systems, no clear trend between the phantom thickness and the MSD accuracy could be observed. For instance, the accuracy of DWSDM (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.

*Rando Alderson phantom (set-ups 6 to 9)*

Results of the PA irradiations of the RA phantom (set-up 10) were expected to be identical to the irradiations of PMMA thicknesses of about 20 and 25 cm (set-ups 4 to 5). This was, in general, not observed. This could be in part explained by a combination of system-specific algorithms and difference in material compositions and equivalent thicknesses, resulting in the selection of a different tube voltage and filtration. Indeed, PMMA is not exactly tissue equivalent and the RA phantom also contain lungs. In addition, the probe of the QC dosimeter was also in the X-ray field for PMMA irradiations but not for RA irradiations. Moreover, some SDM software use height and weight as input for selecting the patient model and backscatter factors. The implementation of PMMA slab and RA phantoms would address that issue.
Three software products (em.dose, OpenSkin and DWSDM flat) could not provide MSD estimates for lateral irradiations because a flat phantom was only used. Among the remaining software products, results were variable for lateral irradiations. For instance, CAATSDOSE and DOSE estimates were in agreement with the measurements for lateral irradiations on all tested systems; RDM estimates were in agreement for the GE system but not for the Siemens; whereas DWSDM ICRP and DTS provided estimates with low accuracy, although good accuracy was observed for all other RA phantom irradiations. This variability is not surprising because there is no information from the modality or



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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 only from the thickness of the compressed mattress. This generally introduces an uncertainty of no more than a few-cm and, based on the inverse square law, results in no more than ~10 % uncertainty in the MSD estimates. On the contrary, the source-to-skin distance cannot be estimated from the table height in lateral irradiations. The source-to-skin distance has therefore to be estimated by other means, for instance using the phantom's contour [7], possibly causing errors of several cm which can result in considerable errors in the MSD estimate.

*Simulated procedures*

On the Canon and GE systems, the performances of the SDM products were generally comparable for the simulated procedures and the fundamental irradiation set-ups on the RA phantom (set-ups 6 to 8) when excluding the lateral set-up (9). This is understandable since the simulated procedures did not include strictly lateral projections (primary and secondary angles from -30° to 50° and -15° to 35°). For the Philips and Siemens systems, however, there appeared to be a slight increase and decrease in the MSD estimate, respectively, for the simulated procedures.
No clear trend could be observed among the MSD estimates produced by a specific SDM for the simulated procedures among multiple X-ray systems. For instance, em.Dose and SkinCare estimates were within 20% of the measurements on the GE system, within 40% on the Canon and Siemens systems, and could exceed 40% on the Philips system. This is not surprising since the RDSRs are not completely standardised among manufacturers. Besides, irradiation settings were not completely identical across the tested systems. In particular, X-ray systems from different manufacturers implement different algorithms for the selection of the tube voltage and beam filtration, and those parameters directly affect the accuracy of the SDM estimates. For the same reasons, the performances of a specific SDM product combined with a single X-ray system were quite consistent. Anthropomorphic phantoms offer the most realistic patient representation. One (DWSDM ICRP) of the three tested software tools implementing anthropomorphic phantoms had one phantom model 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 cause errors in the MSD calculations because the phantom dimensions are used to select the appropriate backscatter factors 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. However, some software missed the MSD region when situated at the intersection of overlapping fields. The dimensions and shape of the MSD region were inaccurate for all SDM software on the Philips system because wedge filters were used by default; most SDM software assumes square irradiation fields. Provided an acceptable reproduction of the dimensions, the dose map would improve if the wedge filters were accounted for, the details of which are available in the RDSRs. Not all colour scales were or could be adapted to the magnitude of the displayed MSD. The latter is an issue for software testing when the delivered doses are kept low because it makes the map difficult to read. On the contrary, this is not of concern for actual procedures because higher



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doses are of interest for patient monitoring and fixed colour scales might be desirable to alert the staff when they reach a specific dose thresholds.

*Comparison with literature*

In Table 5, the benchmarking results as available in the literature for 7 SDM products are summarised and compared with the present study for similar configurations (phantom and systems). To the authors' knowledge, no peer-reviewed article presents studies on the experimental accuracy of CAATSDOSE, CareMonitor, DOSE and OpenSkin. SDM products were validated on one X-ray system; only em.dose and RDM were validated against two systems.
SDM calculations on a specific system as observed in the present study usually showed a tendency to either underestimate or overestimate the measurements, but not both. This was not the case in the literature data with the exception of two studies on DoseMap [10] and DWSDM [18]. The absolute maximum deviation presented for measurements on phantoms were of the same order of magnitude as those presented in the literature. However, the number of procedures or configurations reported in some literature studies were higher [17, 18] and/or included configurations specifically addressing parameters not tested individually in the present study (collimation, table movements, FOV, etc.) [15, 17, 18]. It is worth noting that only Habib-Geryes et al. [17] tested RDM with phantom thicknesses from 12 to 30 cm.
For DTS, the result range presented in [8] for measurements performed on a RA phantom was considerably smaller, although more configurations were investigated. This is likely due to the absence of steep lateral projections and the mattress during the tests. The phantom selection issue as discussed above might also have an influence.
For patient studies with DoseMap [13] [16], em.dose [14] [15] and SkinCare [11], which included between 10 and 86 procedures, the result ranges were considerably larger than observed during simulated procedures in the present study. The absolute maximum deviation, however, was comparable for em.dose [14] [15] and SkinCare [11]

*Table 5: comparison of skin dose mapping (SDM) software results with existing literature. The range of difference between the calculated and the measured maximum skin dose is reported, as well as the tested X-ray system and the type of phantom irradiated (water, polymethylmethacrylate (PMMA), Rando Alderson (RA) or real patients). For the results of the present study, SP refers to simulated procedures on a RA phantom.*

| | Literature | | | | This study | | |
|---|---|---|---|---|---|---|---|
| SDM product | Ref | Range (min; max) | Phantom type (N) | System | Range (min; max) | Phantom type (N) | System |
| DoseMap | [10] | (7% ; 25%) | RA (5) | GE Innova IGS | - (15% ; 26%)<br>- (-9% ; -14%) | - RA (4)<br>- SP (3) | GE Innova IGS 530 |
| | [13] | (-53% ; 76%) | Patients (20) | GE Innova IGS 520 | - (-9% ; -14%) | - SP (3) | GE Innova IGS 540 |
| | [16] | (−48 ; 42%) | Patients (86) | GE Innova IGS 520 | - (-9% ; -14%) | - SP (3) | GE Innova IGS 540 |



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| | | | | | | | |
|---|---|---|---|---|---|---|---|
| DTS | [8] | (-8% ; 11%) | RA (~16) | Toshiba (Canon) Infinix | (6% ; 61%) | - RA (4) | Canon Infinix CF-i biplane |
| DWSDM flat | [18] | (-3% ; 22%) | PMMA (13) | Philips Allura Xper FD 20 | (-15% ; 1%)<br>(13% ; 21%) | - RA (3)<br>- SP (3) | Philips Allura Xper |
| DWSDM ICRP | [18] | (-3% ; 25%) | PMMA (13) | Philips Allura Xper FD 20 | (-15% ; 50%)<br>(10% ; 17%) | - RA (4)<br>- SP (3) | Philips Allura Xper |
| em.dose | [14] | (-36% ; 53%) | Patients (40) | Philips Allura Xper FD 10 | (27% ; 49%) | SP (3) | Philips Allura Xper |
| | [15] | (-6.% ; 25%)<br>(-43% ; 34%) | RA (8)<br>Patients (34) | Siemens Artis Zeego | (-17% ; -13%)<br>(-34% ; -26%) | RA (3)<br>SP (3) | Siemens Artis Zee biplane |
| RDM | [17] | (-19% ; 21%) | PMMA (17) | GE Innova IGS 540 | (-4% ; 14%)<br>(-33% ; 4%) | PMMA (5)<br>RA (4) | GE Innova IGS 540 |
| | [17] | (-24% ; 3%) | PMMA (17) | Siemens Artis Zee | (2% ; 45%)<br>(-66% ; -14%) | PMMA (5)<br>RA (4) | Siemens Artis Zee biplane |
| SkinCare | [11] | (-37% ; 44%) | Patients (10) | Siemens Artis | (-35% ; -22%) | SP (3) | Siemens Artis Zee biplane |

### 4.3. Acceptance protocol, acceptability criteria and QC

The protocol presented in this article could be used as a basis for developing acceptance testing and quality control protocols. Details of the measurement protocol as designed in the frame of the VERIDIC project are presented in the supplementary material.

An acceptance protocol could contain all the 9 irradiation set-ups presented in this article and three short, simulated procedures. The protocol should be completed with fundamental irradiation set-ups focusing only on the effect of the collimation and table movement because they can cause field overlap. In the present study, those parameters were only varied in the simulated procedures. If necessary to limit the number of measurements, irradiations set-ups with 15 and 25 cm PMMA phantoms (set-ups 2 and 4) could be replaced with set-ups addressing table movement and collimation. The heel effect should also be investigated if larger FOV are used without collimation in clinical practice because it could be significant.

A QC protocol could be based on a limited number of fundamental irradiation configurations using only a single phantom which should be representative of most local patients, e.g., a 25 cm thick PMMA slab phantom. Ideally, the Acceptance protocol should be performed post installation and prior to releasing the SDM software product into clinical use. The QC protocol should be performed following the frequency of the interventional X-ray system QC and following any major software upgrade.



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Qualitative criteria to assess the dose map acceptability and performances are also necessary for safe implementation of SDM products into clinical use. However, this is a complex task which deserve dedicated research. In particular, those criteria should cover the dimensions of the dose regions, their position and their absolute values. These could eventually be combined into a single quantitative score.
No acceptability criteria currently exist for SDM accuracy. In this work, a 40%-deviation from the measurements was selected as a reference value for analysing the accuracy of the MSD values. The maximum deviation value is based on a combination of the measurement uncertainty and the maximum acceptable deviation for the $K_{a,r}$ value made in the European Commission guidelines [30]. It is reasonable to consider that the proposed value of the maximum deviation acceptable for the MSD estimate should, at least, be equal to the maximum deviation for the $K_{a,r}$, which is a fundamental input parameter for the MSD calculations. Obviously, this range is wide and a more stringent value is desirable for implementation of the SDM products in clinical practice. While several European countries have already implemented values lower than 35% for the $P_{KA}$ and $K_{a,r}$ accuracy in their legislation, lower deviation ranges might be difficult to achieve at the present time. This is due to the level of data availability in the RDSRs, their lack of standardisation across manufacturers and the product performances observed in the present study.
A conservative estimate (overestimation) of the MSD is preferable for radiation protection purpose; which could be translated into acceptability criteria. In addition, the acceptability criteria could be adapted with respect to the magnitude of the dose, thereby more stringent criteria could be applied to higher doses relevant for induction of skin injuries after one or multiple procedures.
Ideally, the MSD estimates should not exceed the maximum deviation in any of the fundamental irradiation set-ups or the three clinical procedures. Nevertheless, those criteria should be adapted to the local clinical practice and treated patients. A higher deviation could therefore be acceptable for very specific cases. For instance, for fundamental set-ups 4 and 5 if no thin and/or paediatric patients (with thicknesses equivalent to 15 and 10 cm PMMA, respectively) are treated. Similarly, fundamental set-up 9 is acceptable if no lateral projections are to be used in clinical practice or if the exposure from lateral projections can be neglected.
Furthermore, knowledge of the SDM product calculation algorithm, especially the parameters customisable to the local specificities (for instance, table and mattress attenuation or $K_{a,r}$ calibration factor(s) of the X-ray system), should not be overlooked because it can help the medical physicist to improve the accuracy of the MSD estimates.

## 5. Study limitations

The main study limitations are related to (i) the inherent properties of the dosimetric measurement systems and (ii) the calculation methodologies of the SDM tools.
(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 [26]. For TLDs and films, the energy dependence remains the dominant factor; whereas solid state QC dosimeters usually have a considerably smaller energy dependence, these might however 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 convert 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 beam qualities encountered in interventional cardiology, the ratio can vary between 1.02 and 1.12 [29]. Using a fixed value (1.06) can lead to a maximum error of 5 % [29]. This is also the value implemented in most SDM software products [12]



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A PMMA slab phantom was used because this is frequently used for QC measurements and thus readily available to most medical physicists. This phantom is not exactly water-equivalent. As showed by Benmakhlouf et al [33], 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 BSFs determined for water.

(ii) The $K_{a,r}$ accuracy and the table transmission factor as measured on the systems were used for the calculations using offline SDM products if those parameters could be readily input. Default values were used as defined in the SDM products at the time of the calculations for parameters not available in the RDSRs. This might put those SDM products which allow additional adaptation of the calculation settings to a specific X-ray system, at a disadvantage in the comparison. The dose maps were also produced with default values although some SDM products have adaptable settings for improved visualisation. It is worth noting that online software products such as DTS and DoseMap contain transmission (and backscatter) models based on multiple measurements [8, 10], but the accuracy of those models was not specifically evaluated.

In addition, the selection of a single transmission factor value in most offline SDM products can dramatically affect the accuracy of the calculations. Wide ranges of table and mattress transmission factors can be encountered in practice, as observed in the present study on four systems with values ranging from 54% to 90% or as reported by DeLorenzo et al. [34] with measurements on three systems ranging from 59% to 91%. The same is true for the $K_{a,r}$ calibration factor which can considerably influence the dose. This factor depends on the beam quality [35]; however, most SDM products only permits one value as input. Assuming up to 35% deviation of the displayed $K_{a,r}$, as per the $P_{KA}$ deviation tolerated by the European Commission guidelines [30], the selection of a single calibration factor can have a great effect on the calculated dose. It is also worth mentioning that there is a specific tag for reporting a single $K_{a,r}$ calibration factor but it is rarely – properly - populated in the RDSRs.

## 6. Conclusions

Measurements following a common protocol were performed on four interventional X-ray systems and compared with MSD calculations of up to eight of 10 SDM products, depending on compatibility. Acceptability criteria were also discussed.

The MSD estimates generally agreed with the measurements within ±40% for fundamental irradiation set-ups and simulated procedures. However, no SDM product could provide MSD estimates within ±40% for all combinations of configurations and - compatible - systems. Only three out of 10 SDM products produced MSD estimates within ±40% of the measurements for all tested configurations on at least one compatible X-ray system. The accuracy of the MSD estimate for lateral irradiations was quite variable and could be very poor (up to 66% underestimation). Most SDM products produced maps which qualitatively represented the dimensions, the shape and the relative position of the MSD region. Some software products, however, missed the MSD region when situated at the intersection of multiple fields, which is of radiation protection concern.

The main limitations of the SDM software products are currently the level of data available in the RDSRs, the lack of harmonisation among manufacturers, the difficulty to select specific examination parameters and – QC - phantom models, and the need for accurate techniques for determining the patient body contour and position. Due to these limitations, it is very challenging to establish a common protocol for QC and acceptance testing. The present protocol could be seen as a basis for an interim solution while issues are addressed by the manufacturers.



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## Conflict of interest:

C. Maccia and F. Malchair developed CAATSDOSE. O. Ciraj Bjelac supervised the development of SkinCare.

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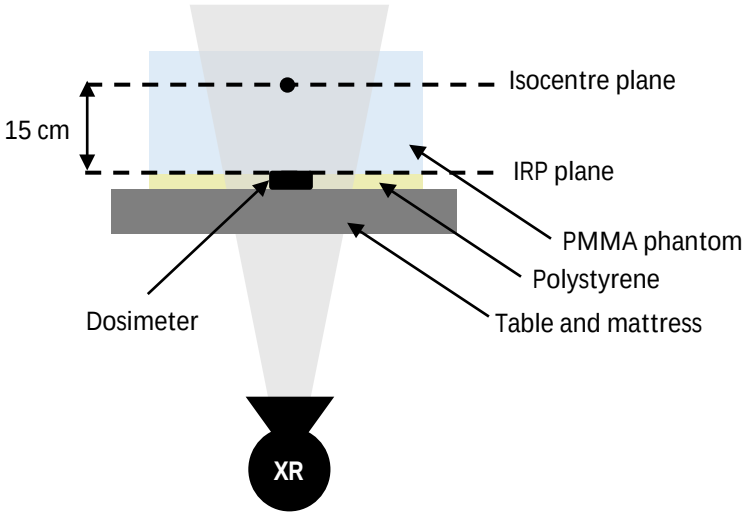


Figure 1: Experimental set-up for posterior anterior irradiation of a phantom.

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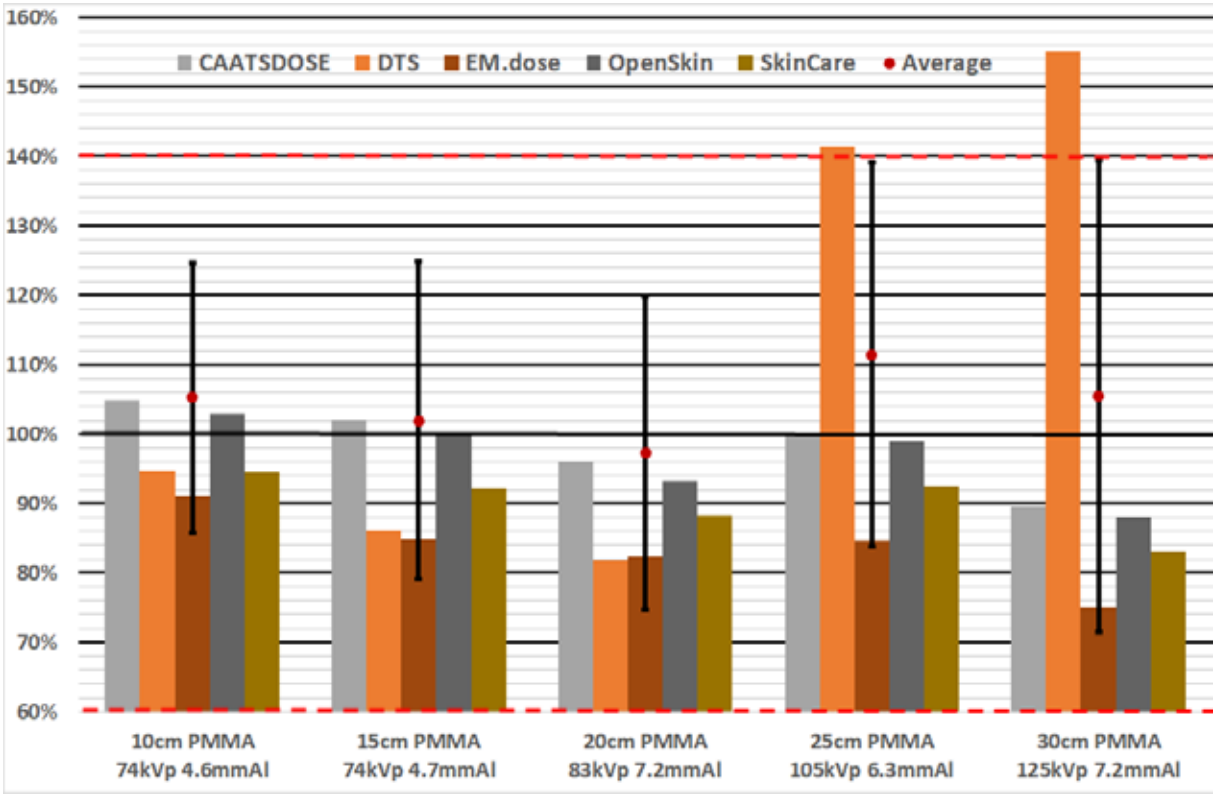


Figure 2: Ratios of the calculated and the measured maximum skin dose values (Equation 1) for polymethylmethacrylate (PMMA) thicknesses ranging from 10 to 30 cm on a Canon Infinix CF-i biplane system. Tube voltage (kVp) and half-value layer values (mmAl) are reported. Red horizontal bars represent the ±40% deviation range. The standard deviation is represented as error bars drawn from the average estimate.

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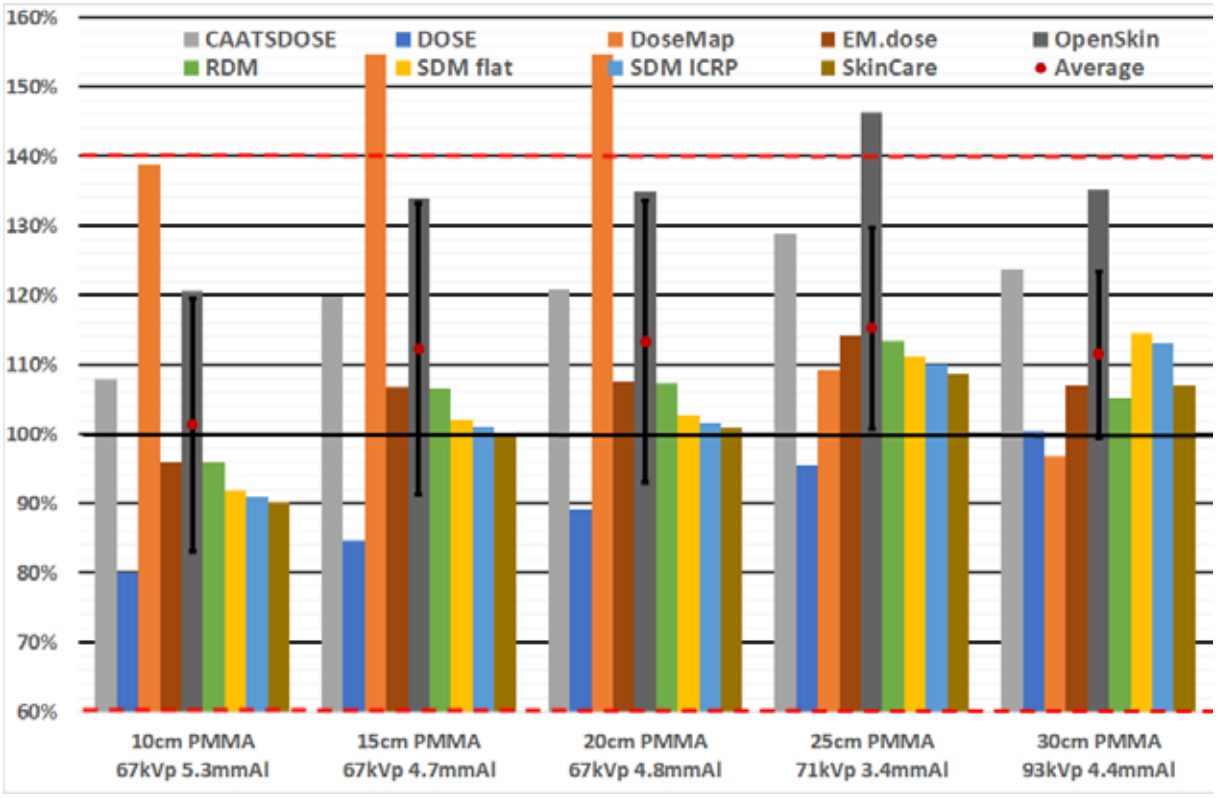


Figure 3: Ratios of the calculated and the measured maximum skin dose values (Equation 1) for polymethylmethacrylate (PMMA) thicknesses ranging from 10 to 30 cm on a General Electric Innova IGS 540 system. Tube voltage (kVp) and half-value layer values (mmAl) are reported. Red horizontal bars represent the ±40% deviation range. The standard deviation is represented as error bars drawn from the average estimate.

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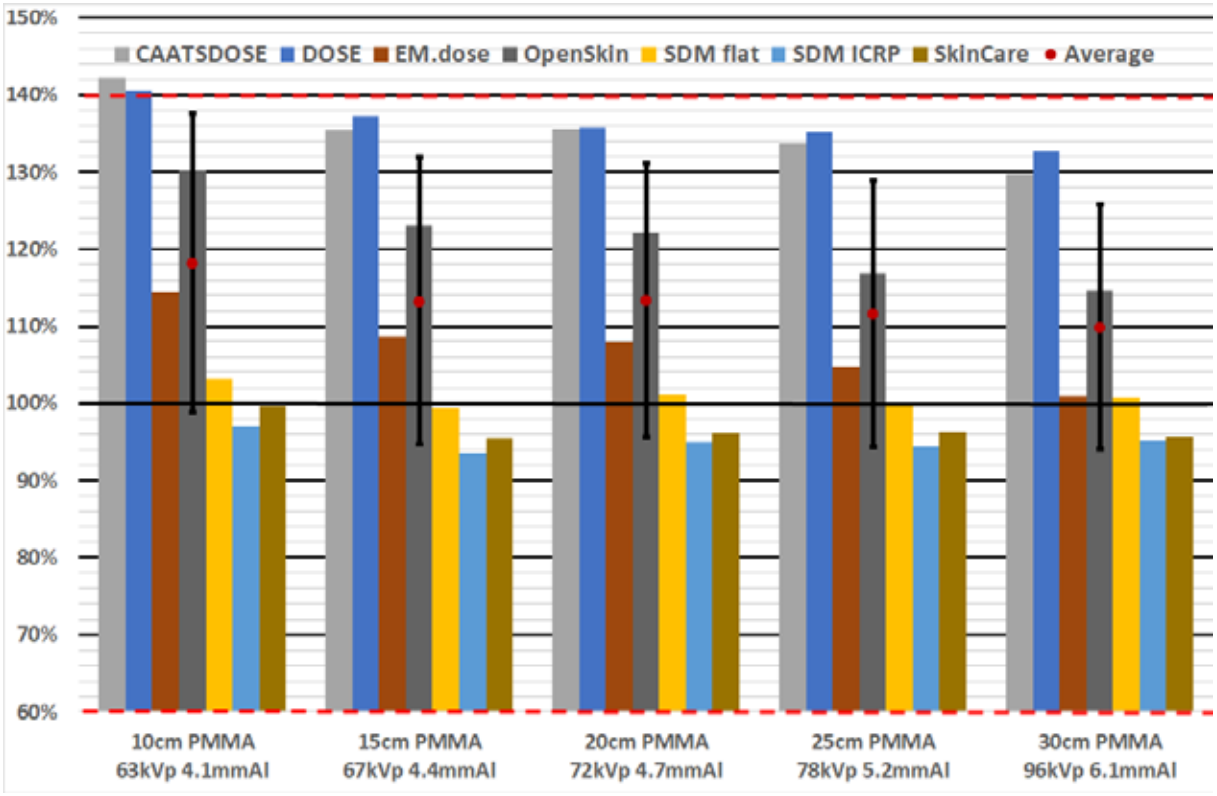


Figure 4: Ratios of the calculated and the measured maximum skin dose values (Equation 1) for polymethylmethacrylate (PMMA) thicknesses ranging from 10 to 30 cm on a Philips Allura Xper system. Tube voltage (kVp) and half-value layer values (mmAl) are reported. Red horizontal bars represent the ±40% deviation range. The standard deviation is represented as error bars drawn from the average estimate.

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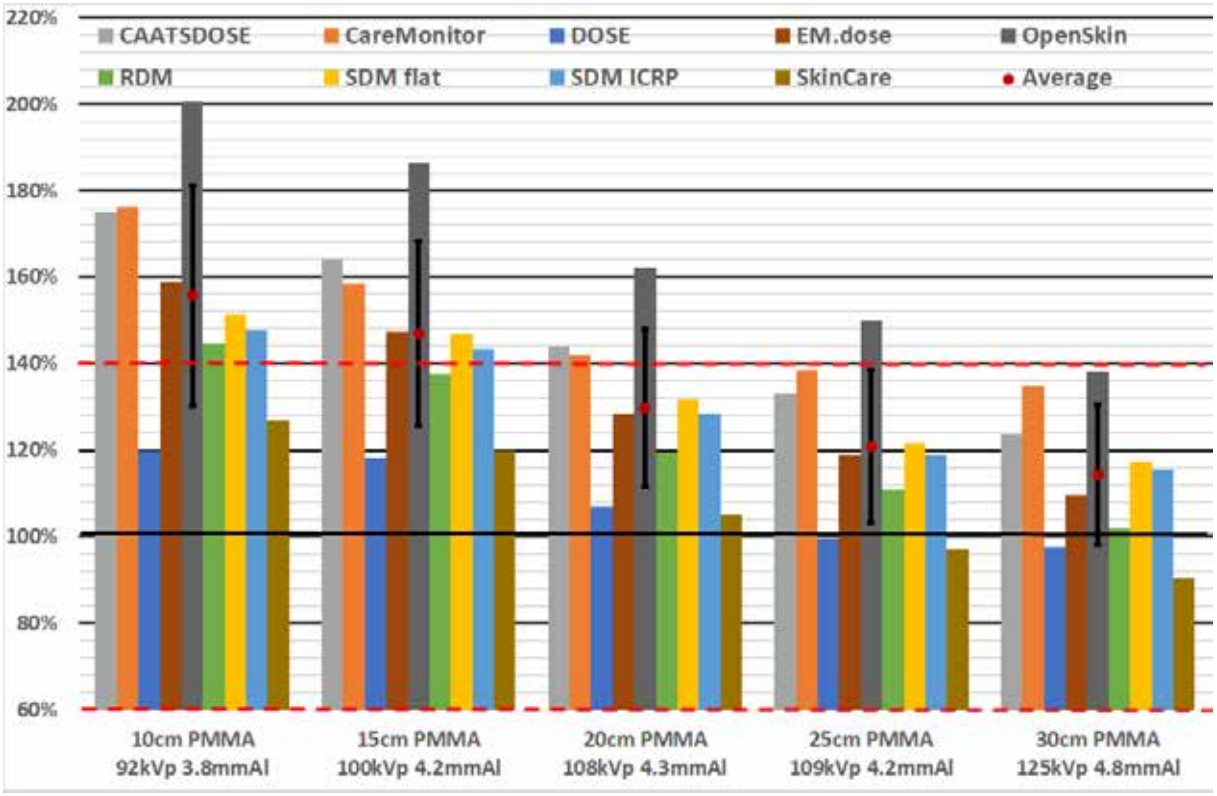


Figure 5: Ratios of the calculated and the measured maximum skin dose values (Equation 1) for polymethylmethacrylate (PMMA) thicknesses ranging from 10 to 30 cm on a Siemens Artis Zee biplane system. Tube voltage (kVp) and half-value layer values (mmAl) are reported. Red horizontal bars represent the ±40% deviation range. The standard deviation is represented as error bars drawn from the average estimate.

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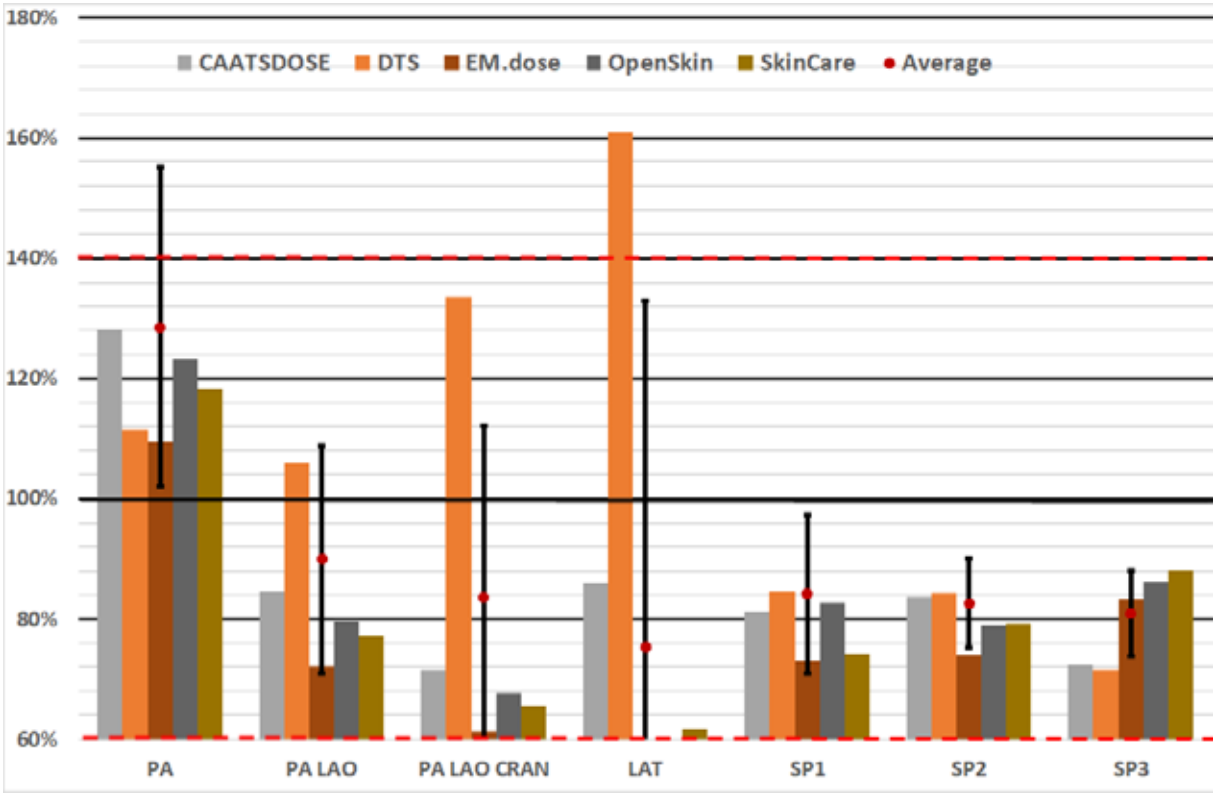


Figure 6: Ratios of the calculated and the measured maximum skin dose values (Equation 1) for fundamental irradiations set-ups 6 to 9 and simulated clinical procedures (SCP) 1 to 3 on a Canon Infinix CF-i biplane system. Projections are posterior anterior (PA), left anterior oblique (LAO), lateral (LAT) and cranial (CRAN). Red horizontal bars represent the ±40% deviation range. The standard deviation is represented as error bars drawn from the average estimate.

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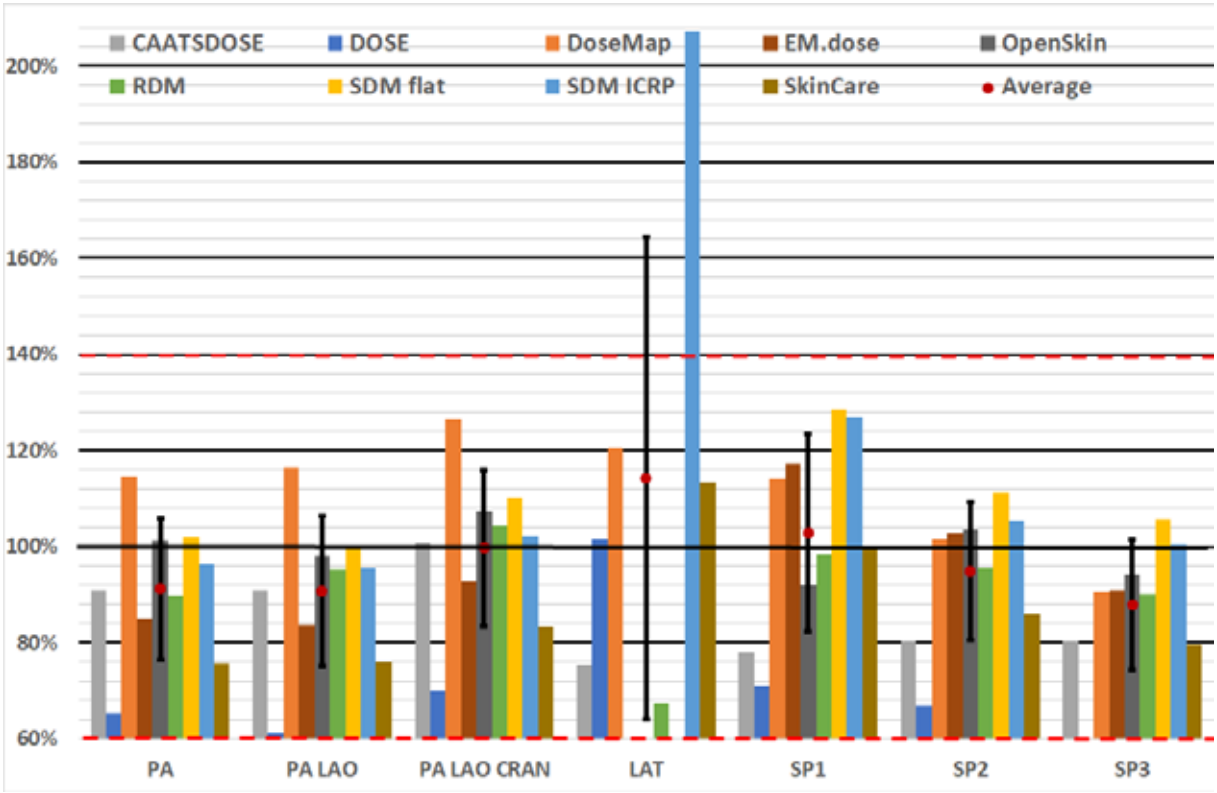


Figure 7: Ratios of the calculated and the measured maximum skin dose values (Equation 1) for fundamental irradiations set-ups 6 to 9 and simulated clinical procedures (SCP) 1 to 3 on a General Electric Innova IGS 540 system. Projections are posterior anterior (PA), left anterior oblique (LAO), lateral (LAT) and cranial (CRAN). Red horizontal bars represent the ±40% deviation range. The standard deviation is represented as error bars drawn from the average estimate.

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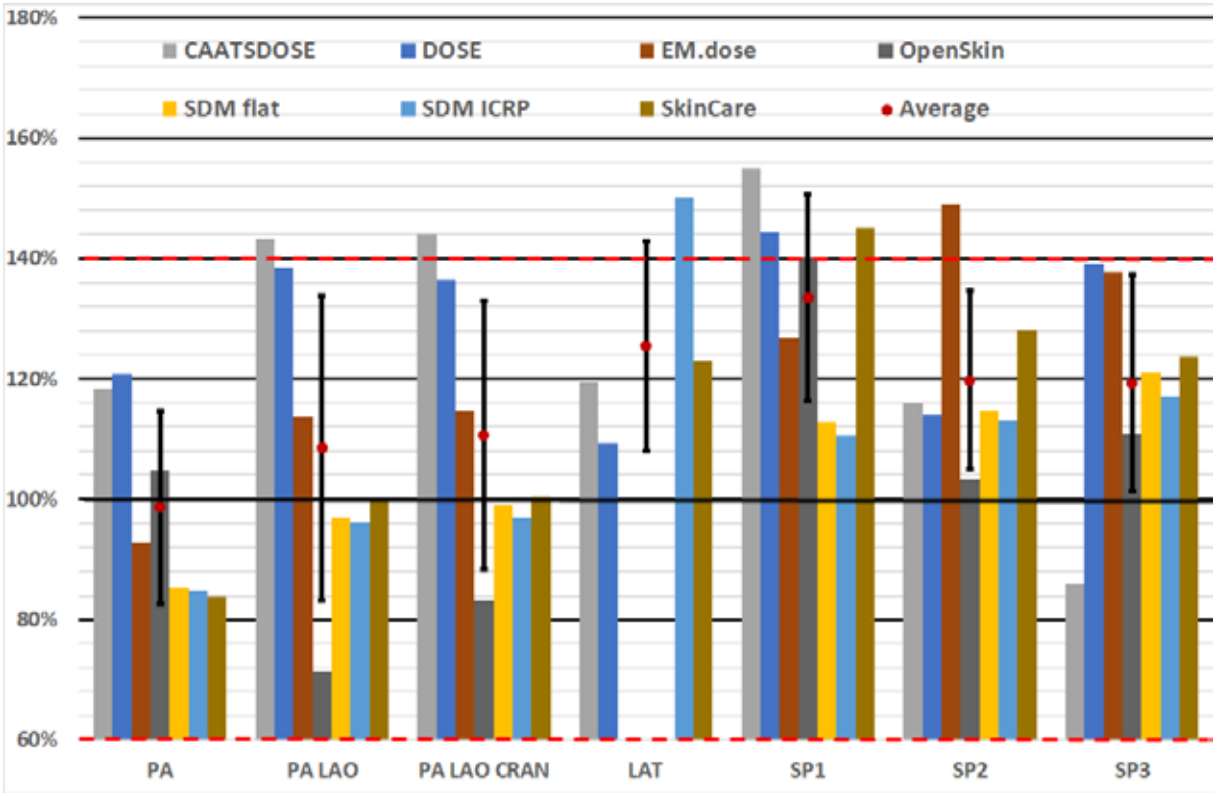


Figure 8: Ratios of the calculated and the measured maximum skin dose values (Equation 1) for fundamental irradiations set-ups 6 to 9 and simulated clinical procedures (SCP) 1 to 3 on a Philips Allura Xper system. Projections are posterior anterior (PA), left anterior oblique (LAO), lateral (LAT) and cranial (CRAN). Red horizontal bars represent the ±40% deviation range. The standard deviation is represented as error bars drawn from the average estimate.

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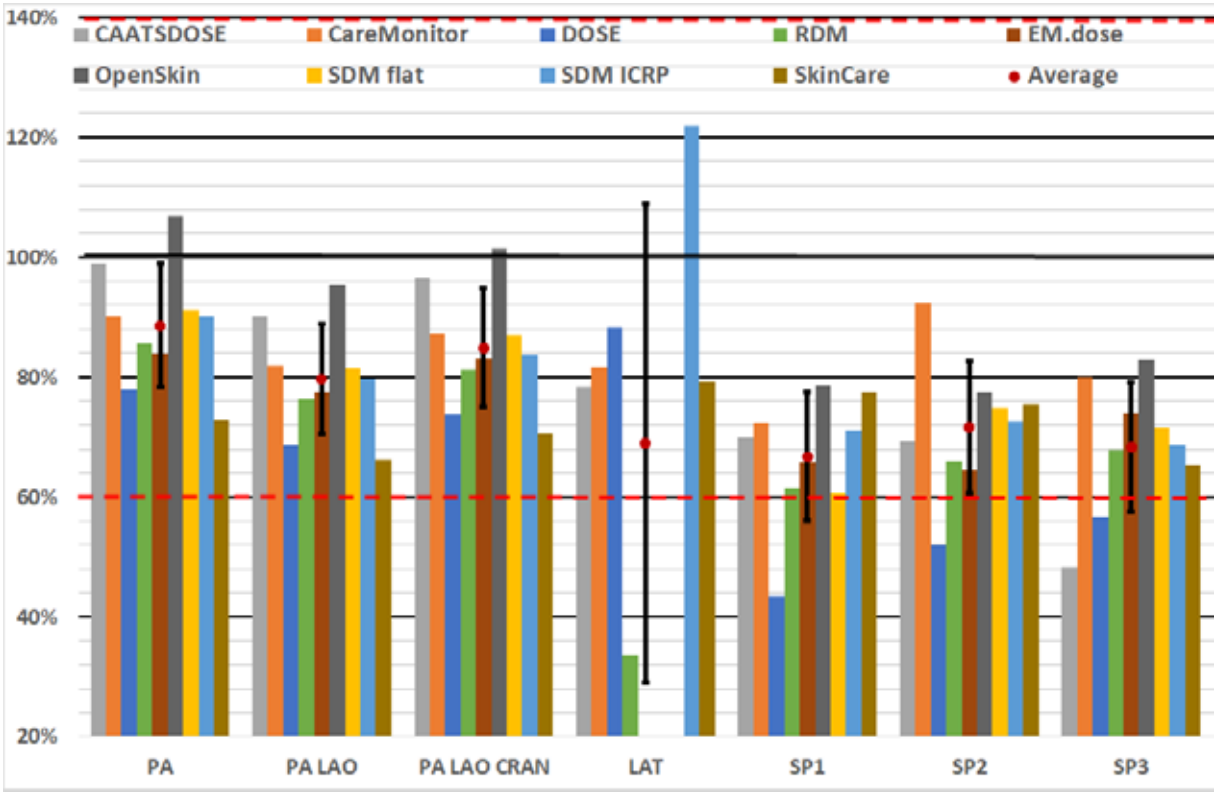


Figure 9: Ratios of the calculated and the measured maximum skin dose values (Equation 1) for fundamental irradiations set-ups 6 to 9 and simulated clinical procedures (SCP) 1 to 3 on a Siemens Artis Zee biplane system. Projections are posterior anterior (PA), left anterior oblique (LAO), lateral (LAT) and cranial (CRAN). Red horizontal bars represent the ±40% deviation range. The standard deviation is represented as error bars drawn from the average estimate.

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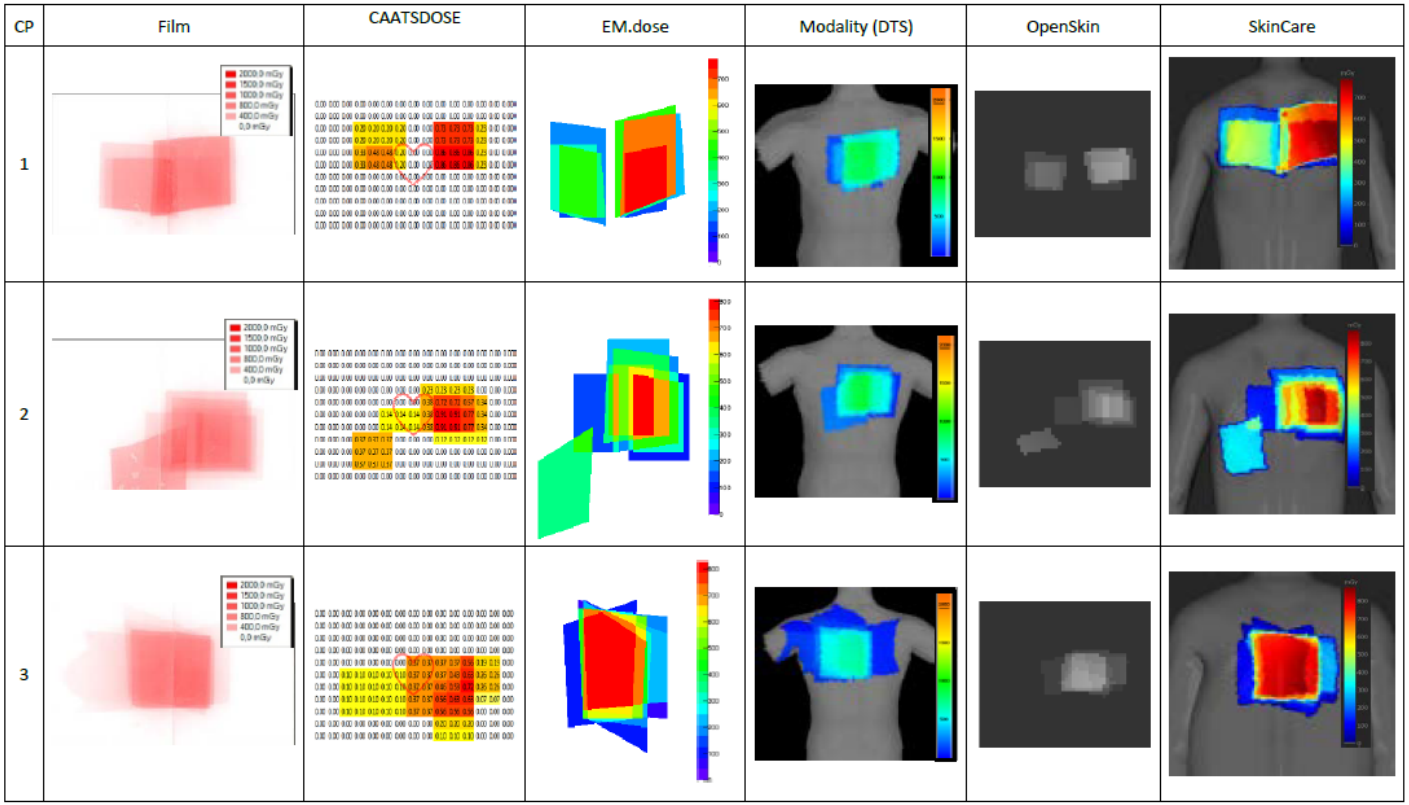


Figure 10: Measured and calculated dose maps for three simulated clinical procedures using a Canon Infinix CF-i biplane system. Patient's head points towards the top of the maps; patient's left is on the left side of the maps. Limited modifications of the dose maps (such as cropping or reorientation) were performed in order to facilitate a qualitative comparison.

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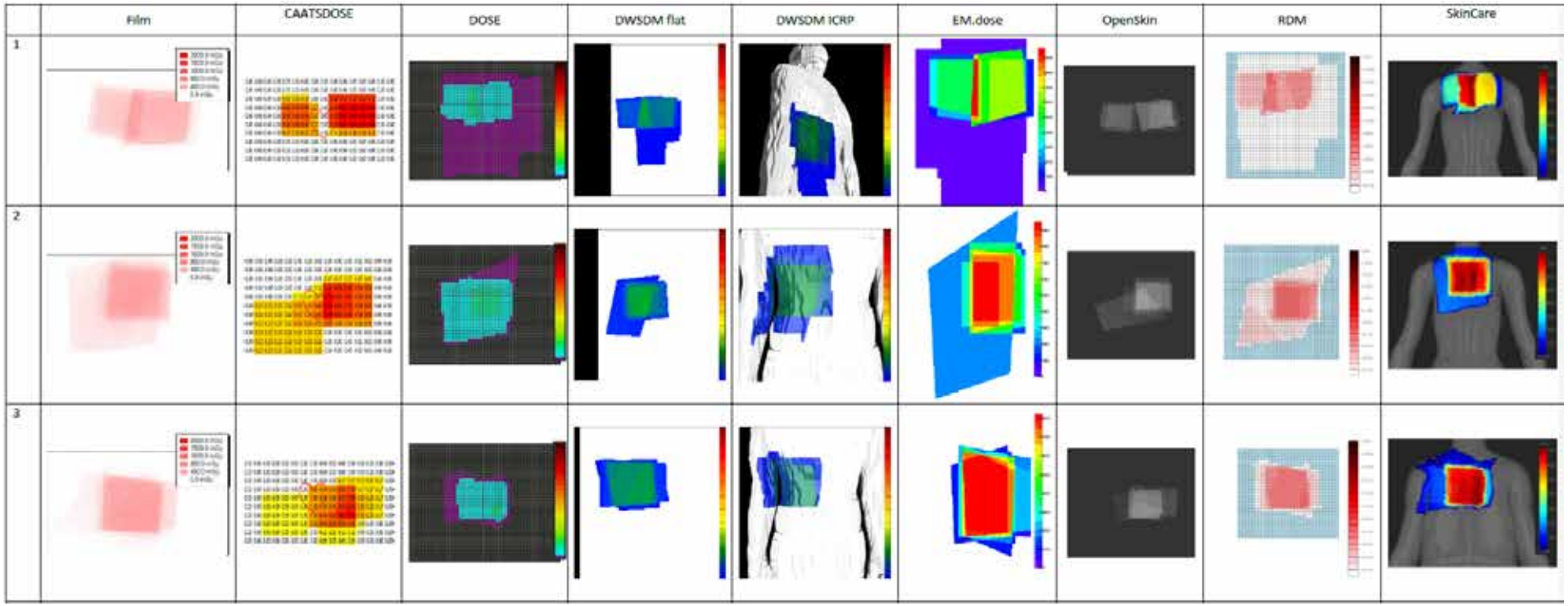


Figure 11: Measured and calculated dose maps for three simulated clinical procedures using a General Electric Innova IGS 540. Patient's head points towards the top of the maps; patient's left is on the left side of the maps. Limited modifications of the dose maps (such as cropping or reorientation) were performed in order to facilitate a qualitative comparison.

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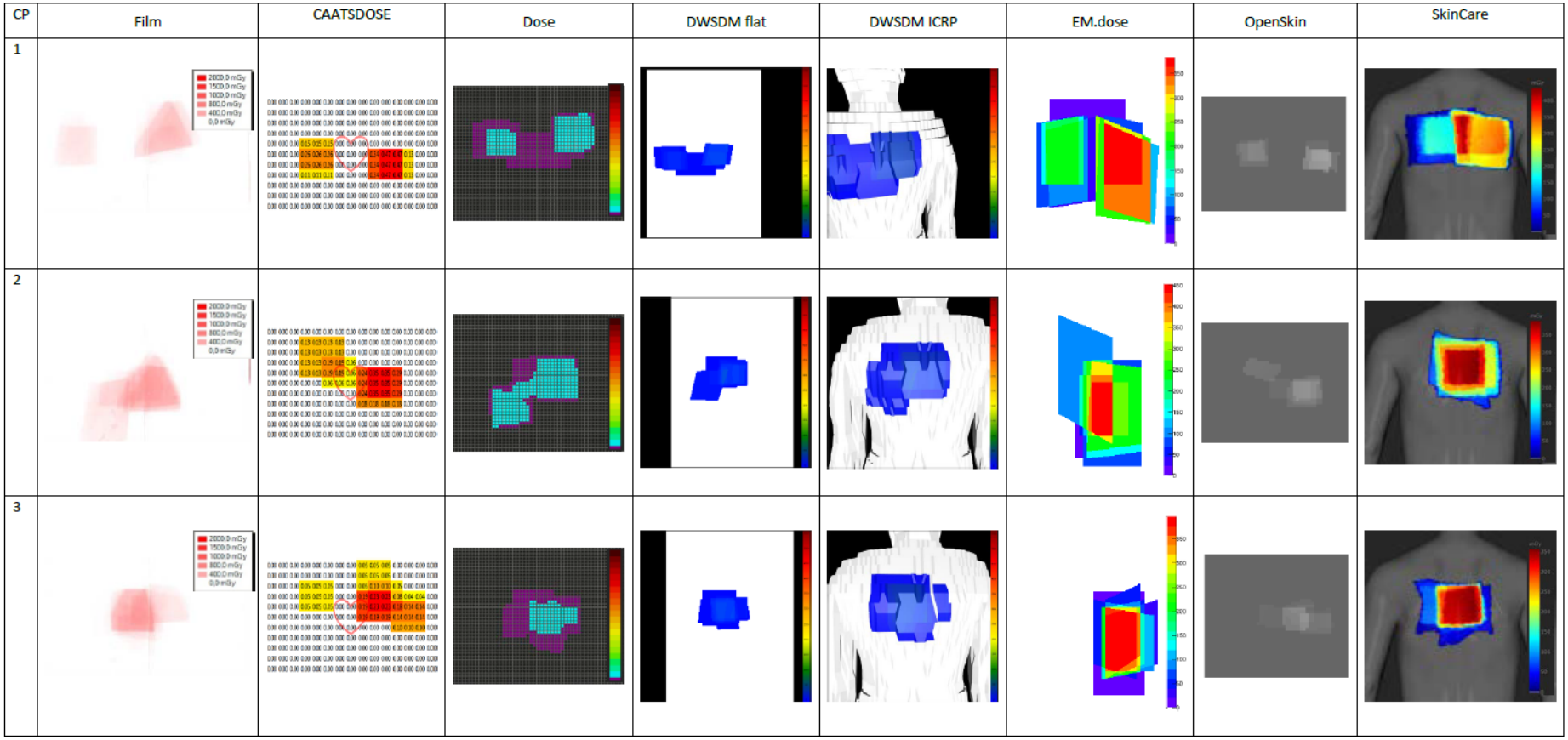


Figure 12: Measured and calculated dose maps for three simulated clinical procedures using a Philips Allura Xper. Patient's head points towards the top of the maps; patient's left is on the left side of the maps. Limited modifications of the dose maps (such as cropping or reorientation) were performed in order to facilitate a qualitative comparison.

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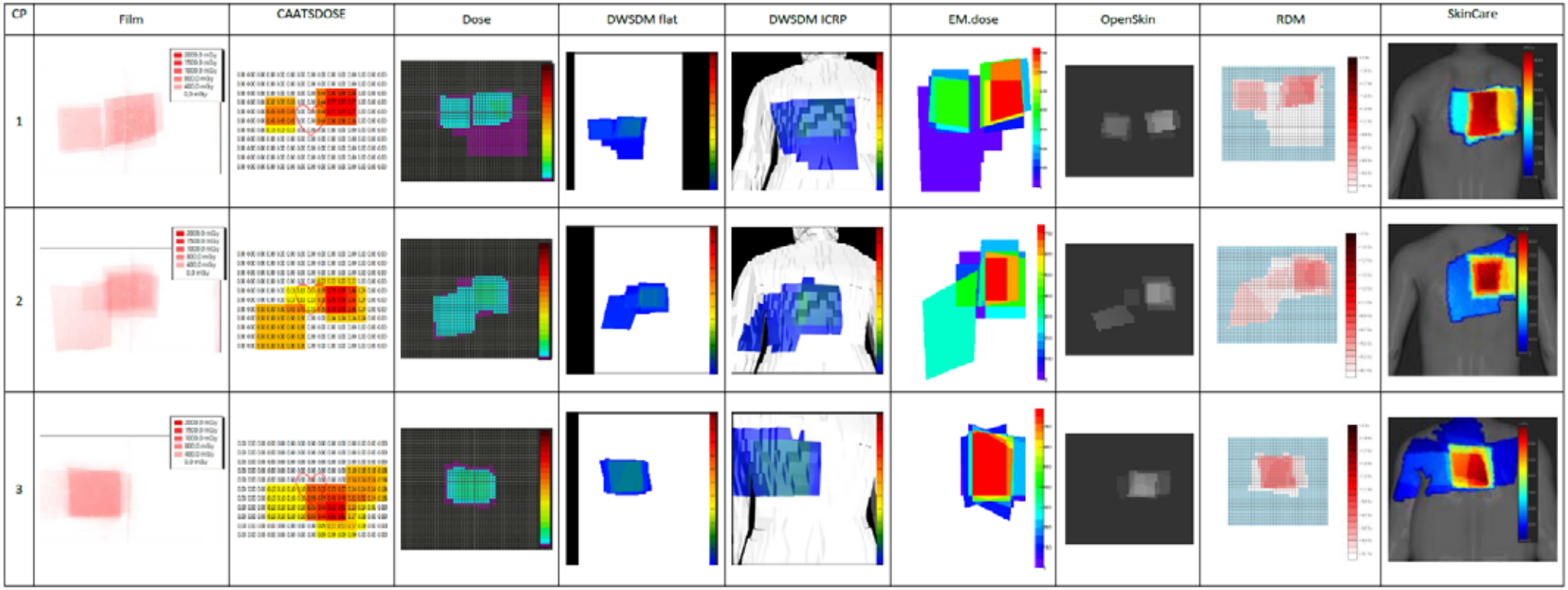


Figure 13: Measured and calculated dose maps for three simulated clinical procedures using a Siemens Artis Zee biplane system. Patient's head points towards the top of the maps; patient's left is on the left side of the maps. Limited modifications of the dose maps (such as cropping or reorientation) were performed in order to facilitate a qualitative comparison.

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