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D9.114- Report summarizing the experimental and clinical findings when using the online dosimetry application

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Content

Abstract

The objective of the PODIUM project is to develop a user-friendly online tool to calculate the radiation dose to workers. This is done by combining positioning information from individual staff members using the developed Indoor Positioning System (IPS) based on the Microsoft Kinect 3D camera as well as information on the radiation field and the geometry of the room.

The main aim of Work Package 4 is to validate the tool in hospitals, in particular in interventional radiology. In order to accomplish this, the work was divided into two main tasks. The first task was to test the online application in an experimental set-up using clinical X-ray equipment and the second was to test the tool during routine or typical clinical interventions. These tasks, involving experimental and clinical tests, have been used to indicate development needs in order to understand the full clinical relevance of the online dosimetry application. A summary of both has been presented in the deliverable reports D9.110 and D9.113.

This report explores the possibilities and limitations of the application taking into account the clinical situation. The goal of this report is to build on lessons learned from the experimental and clinical validation presented in D9.110 and D9.113 and to use this learning to identify future improvement needs for the online dosimetry application in hospitals.

I. Introduction

The goal of this project is to develop an online software tool that will calculate radiation doses to workers by combining information on staff (and position of objects such as radiation protection screens) with information on the field of scattered radiation and the room geometry. This will form the basis of our indoor positioning system (IPS).

The project work package (WP) 4 is focused on validating the IPS and the online tool for use in hospitals, especially in interventional radiology and cardiology, where the highest doses to staff in medicine can occur. For interventional procedures, the aim is that the online system will improve the knowledge of radiation dose to staff, not only their whole-body dose, but also the radiation dose for the lens of the eye and the hands.

The complete PODIUM system (both hardware and software) must meet the demands of the clinical environment and be feasible to use in hospitals. The radiation dose measurements must be accurate, at least within a factor of 2 which is accepted for physical dosimeters. The use of the IPS must meet safety requirements when introducing technical devices into operating rooms (some interventional rooms are classified as operating theatres) and practical issues concerning handling of the tool by the hospital staff must be addressed. Privacy and ethical concerns are highly relevant in this scenario with a camera monitoring movement in the room. Operating rooms will vary in size and the installed equipment differs in types and patterns of usage. The clinical team for an interventional procedure can range from two staff members to, in some cases, more than ten, each working at different positions around the patient table. The typical practice of staff and the use of radiation protection techniques e.g. ceiling or table mounted shielding; or staff moving out of the room during image acquisition, can differ between rooms and procedures.

Each of the factors described above has been encountered during the clinical validation tasks of PODIUM and the report that follows is a summary of task 4.3 of WP4: identifying future improvement needs for the online dosimetry application in hospitals.

II. Factors influencing PODIUM future needs

As previously described for PODIUM, we have defined prerequisites for the calculations and the online system and its implications on the validation. An outline of these items is presented in Figure 1 below.

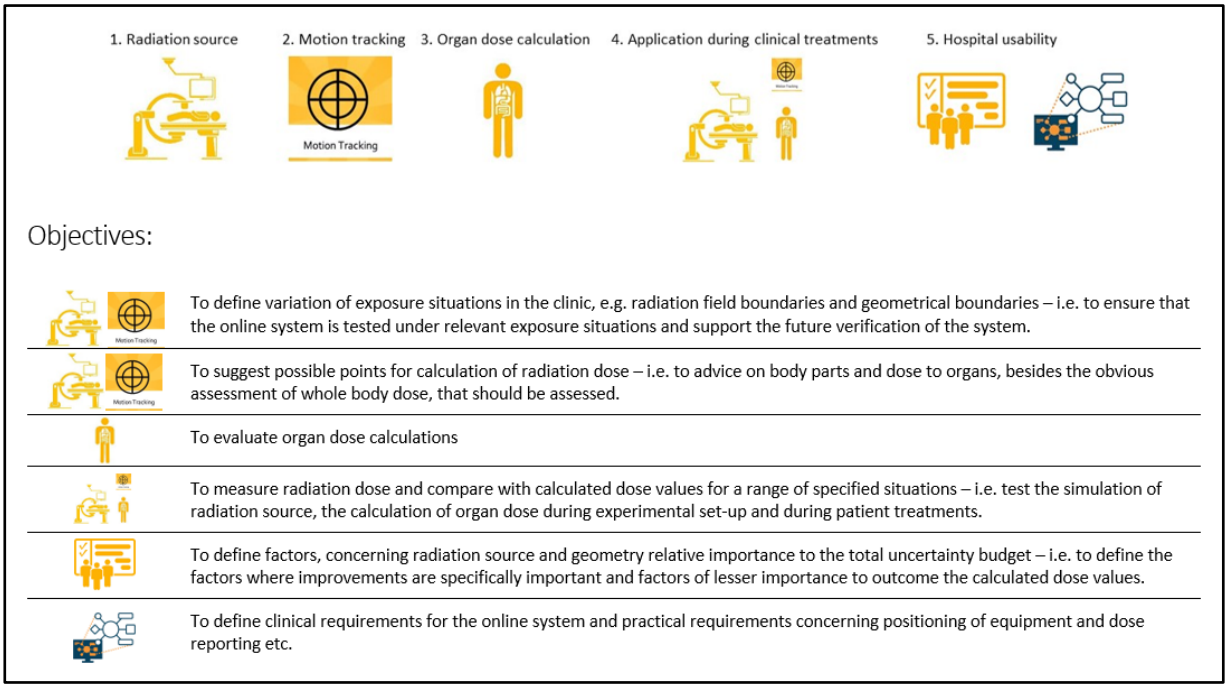


Figure 1: Schematic outline of five factors defined by PODIUM for Interventional Radiology

The experimental and clinical validation tests have provided us with a significant amount of experience in dealing with all five component parts of the application. In this report, each one will be taken in turn and the lessons learned will be described. This has been used to draw up a list of recommendations which should be used to inform the future needs of bringing PODIUM from proof-of-concept to a real world clinical application.

(1) Radiation source

From the early planning stages of the PODIUM project, it was important to ensure that the system was tested under exposure situations that were relevant across a range of interventional radiology/cardiology settings. The radiation source (fluoroscopic X-ray system) should be broadly similar to that found in a typical modern hospital environment. For this reason, two hospitals were chosen as the clinical validation sites (Skåne University Hospital, Malmö, Sweden) and St. James's Hospital (SJH), Dublin, Ireland. Both hospitals are installed with modern interventional angiographic flat-panel detector (FPD) X-ray systems. The clinical case mix was chosen based on procedures that were typically of sufficient radiation dose (in terms of the validation statistics), that were commonly performed around Europe in a similar manner, and where there was also reference dose data available in the scientific literature. Endovascular Aortic Aneurysm Repair (EVAR) procedures performed typically by Vascular Surgeons were selected, along with Coronary Angiogram and Percutaneous Coronary Intervention (PCI) procedures performed in a Cardiac Catheterisation laboratory by Cardiologists.

Both hospitals are large, teaching hospitals with busy workloads. Procedures may be carried out by relatively large numbers of staff in the room, with different roles involved in teaching, training and using equipment. This is relevant to PODIUM as it was known from preliminary tests presented in D9.105 that

the IPS is challenged by complex installations where there is much equipment and many staff members to track.

A description of the installed base of equipment that was chosen for the clinical validation is shown below in Table 1.

Table 1: Equipment used for PODIUM clinical validation

Hospital	Room	Manufacturer	Model	Age of Equipment
Skåne University Hospital, Malmö	Cardiovascular room No. 105	Siemens	Artis Zee	2 years old
SJH, Dublin	Endovascular Theatre	Siemens	Artis Q	4 years old
SJH, Dublin	Cardiac Cath Lab 2	Philips	Allura FD10-10 Bi-plane	5 years old

The age of the equipment is of relevance. A key factor needed for PODIUM is the easy availability of a Radiation Dose Structured Report (RDSR), as defined by the DICOM Standard. These reports include metrics such as Dose Area Product (DAP), as well as detailed geometric and technique information. RDSR outputs are required for interventional fluoroscopic equipment conforming to IEC 60601-2-43 (2nd edition 2010) and therefore they may not be available on older systems. An RDSR contains data on every event on the X-ray system, i.e. every time the foot-pedal or exposure button is pressed; a unique event is created containing a wealth of information on the X-ray primary beam conditions, table positions, angulation and collimation, to name a few recorded parameters. This file of exposure conditions (with a timestamp) is combined with the positional information of the staff member (at the same timestamp) and used in the simulation Monte-Carlo software to simulate the scattered radiation at that time and position, therefore the RDSR file is a mandatory item needed for the Monte-Carlo simulation.

For this reason, a limitation of the PODIUM system is that it will only be compatible with modern systems capable of producing an RDSR. Older systems without an RDSR will not be compatible In addition; even where an RDSR is available on a modern system, the required dose management software may not have been included when purchasing the system. This was the case with one of the systems –also the oldest – from Table 1 above used in PODIUM. This is likely to become less of a problem in future years with Dose Management Systems becoming more and more integral parts of hospital radiology IT systems. However, it should be borne in mind that at this time, quick and easy access to an RDSR at the push of a button may not be an option for many users of interventional systems.

Once an RDSR is available, even though it is a file with a defined standard and format (.SR), it can be converted into other file formats and the contents can vary. The RDSR may typically be available in .DCM or .XLS format and some manufacturers include fields as standard that may be omitted completely or with empty information from other vendors.

For example, in PODIUM the following challenges were encountered with information missing or not included in the RDSR:

- Field size. This information for every event is a key part of simulating staff dose. The size of the field used for the primary beam is linked to the amount of scattered radiation generated, and for larger field sizes the amount of scatter will be increased. On one system used for validation, it was found that the field size was not included as standard. The manufacturer was asked to investigate and agreed the field size should be available, but it was not, and the software version could not be modified or upgraded to enable this. As a result for validation cases on this system, field size was estimated based on stored digital runs only.

- Horizontal movement of the C-arm. For the Monte-Carlo simulation, precise knowledge of the isocenter of the C-arm is required. The isocenter of the primary beam will always be in line with the X-ray tube focal spot and the imaging detector, and is the midpoint between the two. Scattered radiation will vary with distance from the isocenter and thus will affect staff dose. The isocenter will move as the C-arm moves and some of this information will be tracked in the RDSR, such as tube angulation and the source-to-image distance, generally any factors that affect patient dose. The horizontal movement of the C-arm (along the length of the patient) is tracked or displayed in the real-time by the vendor but not usually stored in the RDSR, and was not included in the RDSRs from the systems used for PODIUM clinical validation. As a result, this is a limitation of validation cases and efforts were made to minimize the impact of this by recording C-arm position at some intervals of the procedure, however the precise continuous tracking of the isocenter for every event remains a challenge for future work.

Understanding the format and contents of different RDSRs and determining the key factors needed for PODIUM was another challenge. In order to overcome some of these differences and to obtain files from different systems in a standard format, as part of WP3, a software tool was developed to allow for RDSR files to be (i) anonymized (ii) exported to different file formats and (iii) matched with tracking files from the IPS Kinect camera. This convenient tool is available for different versions of Windows operating systems (32 bit and 64-bit) and has been tested locally on the hospital IT systems used in PODIUM.

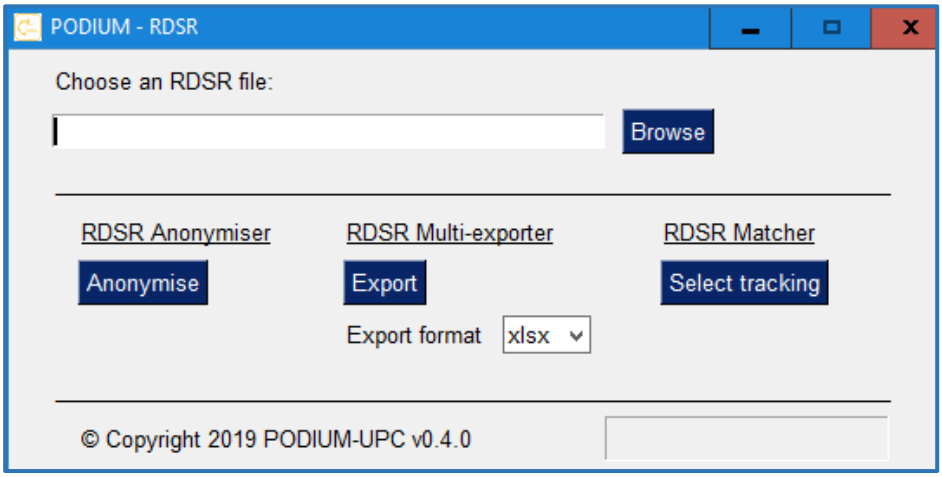


Figure 2: Screenshot of PODIUM RDSR tool

In terms of the radiation source, another factor that is considered vital to PODIUM is the synchronization of the radiation source equipment (e.g. clock setting A on X-ray machine PC) with the IPS software tool (e.g. clock setting on the hospital PC used for PODIUM). The simulation depends on taking each irradiation event (clock A) and matching this (with an accuracy of 1 second) to the file tracking the position of the staff member (clock B). In the first validation experiments, some discrepancies between clock A and clock B were noted, and a correction in terms of minutes and seconds was made to every irradiation event. In Malmö this was not solved and the time had to be corrected manually. However, subsequently in SJH, each vendor was asked to set their X-ray machine PC time to an NTP server which the hospital use for all hospital PCs. This can solve the problem of correcting for any discrepancies and ensures that both clocks used for PODIUM are synchronised to the greatest possible degree of accuracy.

(2) Motion tracking

The Microsoft Kinect™ camera that was chosen for motion tracking has been described previously in (D9.103 and D9.105). One Kinect camera was installed in Malmö and one Kinect camera was installed in SJH, and photos of the installed cameras are shown below. Following some months of validation and work on the IPS to overcome issues (namely occlusions and improving the identification and tracking of staff), a 2 camera solution was installed in the hospital in Malmö as shown below.

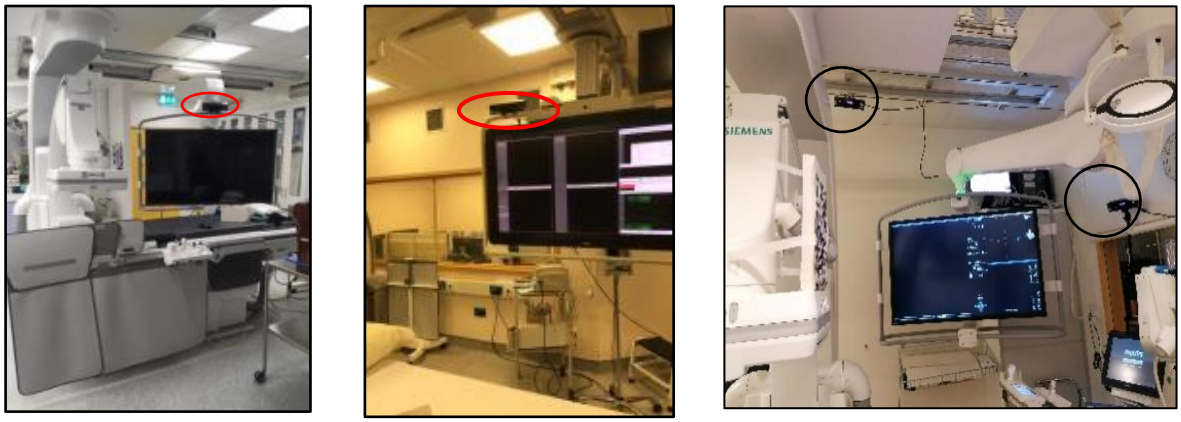


Figure 3: Examples of Kinect installed in SJH (1 camera) and Malmö (2 cameras)

In the Endovascular Theatre of SJH, choosing an ideal location was difficult due to the complex nature of the existing installation. The room is designated as an operating theatre, with few surfaces available to mount additional equipment. The ceiling rails are not ideal as the Kinect with trailing cables may cause an obstruction and limit the full use of the X-ray equipment. The angulation and distance of the Kinect must also be carefully considered to position it tilted downwards towards the staff and within the recommended operating range of around 4.5m (presented previously in deliverable D9.105)

A compromise was chosen and the Kinect was installed mounted on the large X-ray TV monitor. This was ideal in terms of achieving a good view of the main operator; however the TV monitor is not a fixed item and may be moved during cases affecting the calibration of the camera. Efforts were made to overcome this by carrying out calibration measurements using a Kinect calibration software tool (developed by SCK) if the TV monitor moved during clinical procedures. The calibration software is relatively quick and simple to use, however running the calibration software and the Kinect tracking software affected the performance of the IT systems (mainly on the WOW mobile PC). Also during the first calibrations, the co-ordinates had to be manually written down as they were not stored or linked to the tracking files so there is an opportunity for improvement here.

For the two-camera system, an automatic calibration procedure was available. The details are presented in the manual: *Multi Camera Tracking Guide.*

In relation to mounting the Kinect, a custom-made ceiling bracket was also designed and fitted in SJH to allow for some tests to be carried out with the camera in a fixed position. The ceiling bracket had the benefit of a fixed location for the Kinect however in the ceiling there is also more chance of the main operator being occluded by equipment such as the C-arm. It is likely that these challenges in finding an ideal location would be encountered in the majority of interventional rooms.

The IT aspects of the online tool were also considered and aspects of this proved to be a challenge. In each room, it had to be carefully considered where the Kinect (with cables) and PC or laptop (to operate it) would be placed. Power and network points had to be identified. For use in the operating theatre,

the preferred solution is a medical grade PC. One was made available on loan to the PODIUM project from the IT department of SJH. This called a Workstation on Wheels (WOW) and is used widely in the hospital for the Electronic Patient Record (EPR) system). It was upgraded from Win7 to a Windows 10 operating system for use with the Kinect and was considered to be an acceptable and safe IT solution for use in a Theatre in terms of electrical safety and infection control. Even though it met the minimum operating requirements for a Kinect, the performance of this WOW PC with the Kinect was not optimal and on occasion the Kinect would lose connection (over USB 3.0) and therefore some tracking events were not captured. The minimum operating requirements for PODIUM are now detailed in the user manual for the IPS and must be verified before starting to install the system. The file size of tracking files was also considerable (averaging around 50MB x 6 files for some procedures). Therefore storage and backup requirements should be taken into account and efforts made to minimized the amount of data collected where possible e.g. tracking at only 1Hz (compared to 30Hz) and tracking only when the X-ray beam is switched on.

Figure 4: Workstation on Wheels (WOW) medical grade PC in use tracking PODIUM cases in the Endovascular Theatre, SJH

Based on the challenges described here, in the future, a PODIUM-type solution should be designed to be integrated, discrete, cable-free, battery operated and wireless, with fast performance and it should be easy to mount in an X-ray room in a variety of ways. All equipment must be safe to use in the clinical environment (see Risk Assessment below). Along this line, the new wireless depth-camera-computer, such as *Orbbec Persee,* can offer new advantages.

Motion tracking clearly involves tracking or surveillance of persons in the room and this is a core concept of PODIUM. As part of the clinical validation planning, the ethical, legal, privacy and data protection requirements of the hospital (and national requirements) were investigated.

In Malmö an application to the Ethics Committee was submitted and granted. The staff supported the project and some were invaluable for the implementation of the project. In SJH, a series of applications were completed. Hospital research approval was obtained and the necessary Data Protection assessments were completed. An application to the local Research Ethics committee was submitted and approved. Subsequently it had to be amended due to the specific implementation of GDPR in Irish law (for research studies). In short, both patient and staff consent was obtained for all tracked PODIUM procedures using a consent form and participant information leaflet that was GDPR compliant. This requirement for reapproval of all research studies added around 3 months delay to planned start date

for clinical validation measurements. Nonetheless, this was an important and useful part of the research process. It is interesting to note that of around 40 patients and 10 staff who were asked to give written consent, there was only one patient who declined to consent (it is possible that for this patient it was related to a language barrier). In general staff participants were highly supportive and interested in the research. It must however be considered that in the future this may be seen as unwanted surveillance with cameras and a 'big-brother' type approach. Care should be taken to keep all those present in the room fully informed of any camera tracking and privacy / anonymity maintained wherever possible.

It is clear that the system does not function well when there are occlusions blocking the tracking view, or indeed if there are radiation protection features such as a lead-glass shield, or the table-side shielding that cannot be easily tracked with the Kinect. During the validation, efforts were made to track the position of the ceiling screen by an observer who could describe the typical setup and provide sample or representative photos of the setup. In addition, a more quantitative approach was tested using small IMU Meta Motion devices to send gyroscope information via Bluetooth. The automated tracking of the lead-glass shield is one limitation that will need to be addressed for future versions of the application.

Figure 5. Small IMU Meta-Motion devices attached to ceiling lead-glass screen, used to transmit gyroscope data via Bluetooth

Room geometry information is also relevant and useful for PODIUM. The need for this information as part of understanding the clinical environment has been described previously in D9.101. A layout of each clinical room used for validation was prepared and this was done using different methods. For some rooms, a simple plan of the room dimensions was sketched out and distances measured with a laser measure. In other case a more sophisticated method was employed using a mapped CAD drawing. Some key items needed for the validation measurements included the distance from the Kinect to the main operator, and the table height from floor. This description of the room dimensions along with photos was useful in terms of describing the room to the project team however they may ultimately not be required for the PODIUM solution. The minimum requirements in terms of room geometry should be set out clearly for hospital users. The need for a global co-ordinate system for a specific operating room (taking into account the different systems below) has also been noted and it is important to continue to simplify and automate measurements required for this system. This may require close work with X-ray machine vendors in the future to explore live links to their systems. This would allow for the transfer of positional information that may be present in the system but that is not currently stored in the RDSR (e.g. the position of the table is typically included, but not necessarily the position of the C-arm).

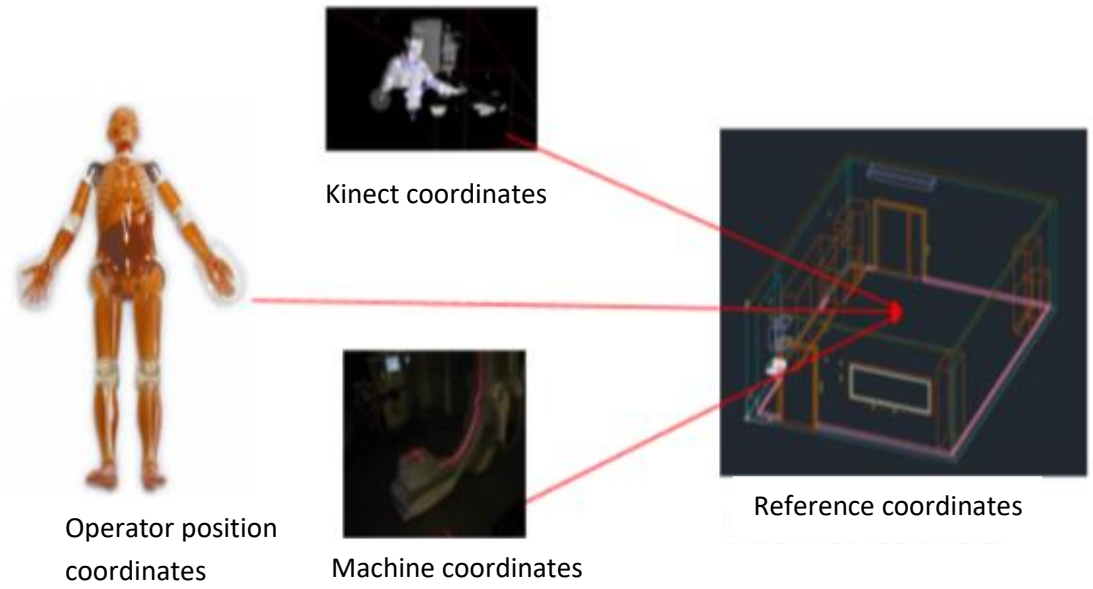


Figure 6. The different systems sending data to the IPS have separate coordinate system

The PODIUM application (WP3) is designed to interact with the Kinect system to control the start and stop of the procedure, the calibration, and to automatically up-load the tracking file for the dose calculation. However to operate in this mode, at least one of the camera computers should have connection to internet and access to the website.

(3) Organ dose calculation

The PODIUM project aimed to establish new methods for organ dose calculation, without wearing personal dosimeters. For the clinical validation measurements, the aim was to ask staff to wear additional eye and finger dosimeters for some cases in order to make a comparison between measured and simulated dose. An example of one type of eye dosimeters used is shown below in Figure 7. Staff were willing to participate in wearing the eye dosimeters with no concerns. There was more reluctance regarding the wearing of extremity or ring dosimeters as staff were concerned about the sterility of the rings and fitting them neatly under their surgical gloves. For this reason, ring dosimeters were not used for the validation measurements. This highlights another possible benefit to the PODIUM approach, where finger dose can be calculated without the need to wear dosimeters that may be a burden for staff.

There were challenges in using passive dosimeters and this is a limitation of the validation method. Passive eye dosimeters were issued for single cases only (to record dose per case, as for the active dosimeters). In many cases, the low doses for one uncomplicated procedure could not be measured and therefore could not be compared with the PODIUM simulations.

In one of the validation cases, the headband eye dosimeter was likely to have recorded a dose above the minimum threshold however it was discarded along with the disposable scrub cap accidentally at the end of the procedure. This is a risk with some dosimeter designs and can occur in routine monitoring programmes. This highlights the benefits to the PODIUM approach, whereby the risk of losing doses from lost physical dosimeters is eliminated, and it may be possible to simulate the dose from very low dose cases:

Figure 7. Eye dosimeter used for PODIUM validation cases (a) PHE Hp(3) headband eye dosimeter

Within PODIUM several methods for dose calculation were investigated and are at present available in the dose application. However, in a final stage, possibly, only one option would be included. On the one hand, a so-called "look-up table" approach based on pre-calculated scattered radiation beams for the fields of interest and fluence to dose conversion coefficients for phantoms of different statures and postures (WP2) has been developed. On the other hand, three Monte Carlo radiation transport codes were also tested: MCNPx, PENELOPE/penEasyIR, MCGPU-IR (WP2).

In order to obtain a fast calculation, MCNPx and PENELOPE/penEasyIR can only provide operational quantities in specific points of the body. MCGPU-IR and the "look-up" table, on the other hand, are designed to calculate organ doses and effective dose. The look-up table approach is based on pre-calculated simulations. For time reasons, the number of simulations had to be limited to some thousand cases, reducing the number of irradiation configuration that were pre-simulated. For example, in the source simulations 11 primary angles were simulated in combination with other parameters. This segmentation reduces the complexity of the look-up tables, but it can impact negatively on the accuracy of the dose assessments. Given the high variability of the exposure scenarios found in IR, we may need to perform more simulations in the future, to complement the tables developed within PODIUM. In the look-up table approach several simplifications are inherently present, like an assumption of $1/r^2$ relation of the fluence towards an isocenter in the patient. Another limitation of the look-up methodology is that it assumes that the shape of the scatter field does not change outside the scattering object, i.e. the body of the patient. This approximation should work as long as there are no major disturbances to the field in the space between the patient body and the doctor. However, it will fail in case shielding (such as ceiling shielding) are placed -correctly- above the patient's body. In order to account for this, an algorithm to reduce the fluences because of lead shielding will have to be developed.

All dose calculation methods are based on the information of the radiation source and the worker tracking and, thus, their accuracy, among other, will depend on the reliability and completeness of the RDSR and the tracking file. From the limitations listed in the previous paragraphs, we could highlight the following difficulties encountered during the testing in the hospitals:

- Loss of identification of the worker, or misplacement of the joints, which generates a wrong position for the calculation. This is particularly important for MCGPU-IR because it uses an anthropomorphic phantom during the calculation.
- In the two-camera system it is foreseen that the main operator (monitored worker) has to raise his hand, so that this person is automatically identified as person to be monitored and its

tracking file up-loaded in the application. However, it was found that the physicians don't always remember to do so, or like to do it, so an alternative solution should be found in the next development.

- Movement of the C-arm, which makes the camera calibration inadequate. As already mentioned, the solution for this problem is to track the C-arm automatically.
- Reset of the patient table position in the X-ray console during the procedure, which disables the automatic correction for Table movements during the procedure.
- Height of the patient table with reference to the floor. The height of the table in the RDSR is usually referred to the isocenter, but for the calculation it is needed relative to the floor in order to position the operator.
- The radiation field dimensions are not always clearly stated.
- The DAP (dose area product) recorded value in the RSDR may not be consistent with the recorded air kerma at the point of reference. The units of these parameters are not always clearly stated and sometimes the values are truncated or with very poor resolution.
- In some procedures the system introduces wedges automatically to reduce the patient dose but this is not recorded. This problem is tackled by using the DAP for the normalization of the calculations and this, in principle, takes into account the effect of the wedges.
- The position of the operator is now fixed during each radiation event, as he normally does not move much since he is pushing the pedal, and the events are very short (seconds). The position of the beginning of the event is taken for the simulations. However, there are cases where the event takes much longer (even up to 10 seconds and longer) and where one of the operators does move significantly. So this should also be taken into account in the next version.

Most of these problems could be overcome if the vendors provided the required data. Apart from this information, it has been found that additional patient data is sometimes not easily available:

- Weight and height of the patient
- Type of procedure, part of the patient body irradiated.

Finally, as indicated in the previous paragraph, one important limitation at this stage, is that the ceiling shielding is not tracked and it cannot correctly be taken into account in the calculations.

(4) Application during clinical treatments

For the clinical validation period, equipment had to be installed in the clinical environment and researchers had to be present before/during and after patient treatments. We have noted previously how important it was to give time and attention to fostering strong relationships with the clinical team in order to have a successful outcome. Much time was spent on raising awareness of the project and discussing any concerns with multi-disciplinary staff. Patient and staff consent was required as part of the Research Ethics approval, due to the surveillance data from the Kinect and the use of a patient RDSR (anonymised version). Even though the depth-map settings on the camera were used (where no persons are identifiable) it was crucial that there was transparency and consent around this aspect of the project. The patient consent process for PODIUM was another task in the busy schedule of the clinical staff, and their input in obtaining consent was invaluable.

For the validation measurements, many tasks had to be completed for tracking each case such as the following:

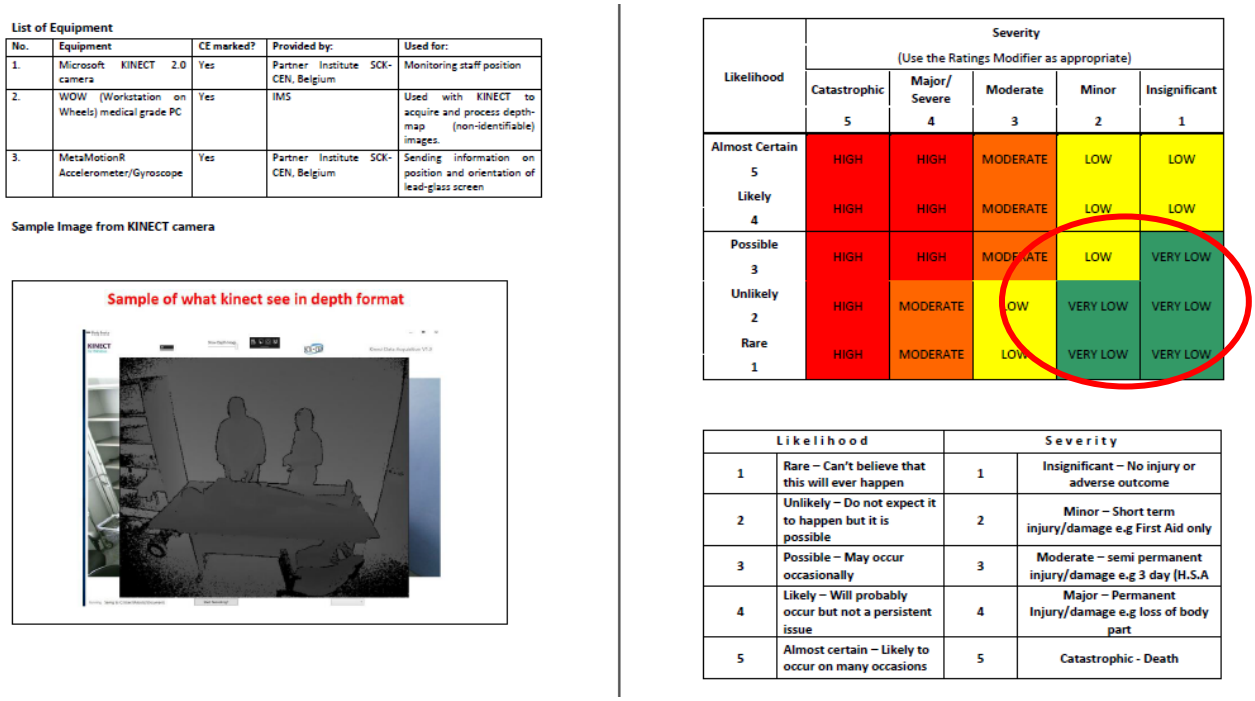
- Before the case
  - Setting up Kinect equipment (connecting cables, checking position, field of view and tilt angle)
  - Setting up PC (checking time setting, testing connection to Kinect, starting tracking software)
  - Obtaining preliminary clinical information about the case (type of procedures, position of staff, possible operators)
  - Issuing Active Personal Dosimeters (APDs)
  - Issuing eye dosimeters
- During the case
  - Starting record function on the software and setting it to depth-map imaging
  - Remaining present in the interventional room or in the X-ray control room, monitoring the equipment and cables to ensure no obstructions for staff
  - Recording many observations, most notably Body ID assigned to main operator(s)
  - Performing software calibration procedure
  - Noting the use of PPE and ceiling lead screen
  - Noting the movement of the C-arm
  - Observing typical positions during key moments such as digital acquisition runs
  - Monitoring the tracking software for disconnections
- After the case
  - Stopping record function on the software
  - Collecting the APDs (and any other dosimeters), recording doses and zeroing
  - Saving and checking the Kinect tracking files
  - Accessing, saving and checking the RDSR file
  - Anonymizing any relevant information
  - Analysing the Kinect files to locate the main operator
  - Preparing the set of analysed files and sharing via secure PODIUM website

These tasks require time and preparation, and although some items (such as issuing APDs) are only relevant for the validation procedures, it should be borne in mind that a future solution of PODIUM must be as time-efficient as possible to setup and track cases. Improvements could be made to optimize the time taken, for example, a permanently installed solution is required with a fixed location for the Kinect, and with all cables connected to the PC. This will reduce the time needed to commence tracking procedures. The PC controlling the system should be outside the X-ray room, in the control room to allow staff remain outside the room where possible. Recording the clinical case information (type of procedures, operators in room, PPE used) should be entered in a user-friendly way in the final PODIUM application, and clinical users should be consulted about the best workflow for this. It is likely that over time in a hospital as room and staff profiles are added to the application database, this process would become more streamlined. The need to record many observations such as the main operator body ID and the movement of the C-arm are time consuming and required a human observer for the validation, and required significant time on analysis after the case, however the problem of tracking the main operator body ID has been improved with the use of an algorithm for the single camera system or with a second camera for the multi-camera system.

Overall, the time taken to use and manage the system should not exceed the time currently required to manage a personal dosimetry system using traditional individual dosimeters.

(5) Hospital usability

Many of the issues facing hospital users have now been discussed. Some concerns with a PODIUM-type approach are likely to arise around the issue of privacy due to the presence of a camera within a clinical room. This must be carefully considered for the future, and include consultation with legal, ethical, data protection and IT experts in the area to develop a solution that will be acceptable. The safety of the installed equipment in the clinical environment is paramount. For the validation measurements, a risk assessment was carried in SJH to review the risks of any equipment being brought into the room. A list of the proposed equipment was prepared and experts in that equipment area from the Medical Physics & Bioengineering team in the hospital were consulted. Areas assessed included electrical safety, laser safety and RF safety. In summary, the risk assessment of the hazards showed no significant risk from the project equipment and appropriate controls were put in place (Figure 8).



List of Equipment

No.	Equipment	CE marked?	Provided by:	Used for:
1.	Microsoft KINECT 2.0 camera	Yes	Partner Institute SCK-CEN, Belgium	Monitoring staff position
2.	WOW (Workstation on Wheels) medical grade PC	Yes	IMS	Used with KINECT to acquire and process depth-map (non-identifiable) images.
3.	MetaMotionR Accelerometer/Gyroscope	Yes	Partner Institute SCK-CEN, Belgium	Sending information on position and orientation of lead-glass screen

Sample Image from KINECT camera

Likelihood	Severity (Use the Ratings Modifier as appropriate)				
	Catastrophic	Major/ Severe	Moderate	Minor	Insignificant
	5	4	3	2	1
Almost Certain 5	HIGH	HIGH	MODERATE	LOW	LOW
Likely 4	HIGH	HIGH	MODERATE	LOW	LOW
Possible 3	HIGH	HIGH	MODERATE	LOW	VERY LOW
Unlikely 2	HIGH	MODERATE	LOW	VERY LOW	VERY LOW
Rare 1	HIGH	MODERATE	LOW	VERY LOW	VERY LOW

Likelihood		Severity	
1	Rare – Can't believe that this will ever happen	1	Insignificant – No injury or adverse outcome
2	Unlikely – Do not expect it to happen but it is possible	2	Minor – Short term injury/damage e.g First Aid only
3	Possible – May occur occasionally	3	Moderate – semi permanent injury/damage e.g 3 day (H.S.A
4	Likely – Will probably occur but not a persistent issue	4	Major – Permanent Injury/damage e.g loss of body part
5	Almost certain – Likely to occur on many occasions	5	Catastrophic - Death

Figure 8. Extract from risk assessment carried out prior to bringing any PODIUM equipment into X-ray rooms. All risks were deemed to be either low or very low.

In Malmö, to carry out the project, various procedures were in place to protect staff and patient integrity. For example, data collected for the project were stored on dedicated research computers. The researchers were also available to do any adjustments, removing equipment etc, if required by the clinic. Any system to be installed integrated into the clinical environment will require other solutions.

Consideration should be given to who, in the hospital setting, will install and manage the equipment for a PODIUM solution. The equipment used is generally not considered electro-medical equipment as it is not intended for treatment on patients, yet it will be close to or within the patient environment. This type of installation will require close collaboration between hospital medical physicists/clinical engineers, radiation safety advisers, radiographers and IT support staff. At an absolute minimum, all equipment must be CE marked. Vendors of X-ray equipment and personal radiation dosimeters should be closely involved in developing future solutions due to their expertise in meeting strict equipment standards. Input from IT experts working in a healthcare is also needed in terms of security, access to third party hardware and software such as the Kinect. The availability of a suitable operating system

within the hospital and a PC (e.g. medical grade may be required) are also vital to the success of this type of solution.

IT requirements are crucial to the smooth installation and functioning of a computer simulated approach to personal dosimetry. The duration of these procedures may vary from about 15 minutes to 2 hours, and in some highly complex cases up to ten hours, which will create very large tracking files. Typical file sizes should be determined and minimized where possible. This issue could be solved by only storing data when the beam is on, using file compression or using different file formats, and even better if one could have on-line information so that the tracking file would not need to be stored.

For a one camera system, with several staff members moving around the room, occlusion is clearly an important issue, and may lead to an incorrect skeleton representation of the operator. If a staff member is partly occluded by the C-arm, by another staff member, or if they are not facing the camera to be 'picked up' by the software, the tracking software will find it difficult to represent their skeleton co-ordinates correctly. Efforts were made to minimize this problem by mounting the Kinect on the TV monitor in the room where occlusions were less of a problem and a clear direct view of the main operator was feasible for most of the case. In some cases where the two operators were very closely working together the system can overlap as shown in the figure below and this separation of staff members could be improved. In addition, for clinical reasons and patient access, in some cases staff will stand on the opposite side of the table to that where the Kinect is pointed. For these cases they are untracked and totally out of the field of view. The multi-camera solution addresses this problem.

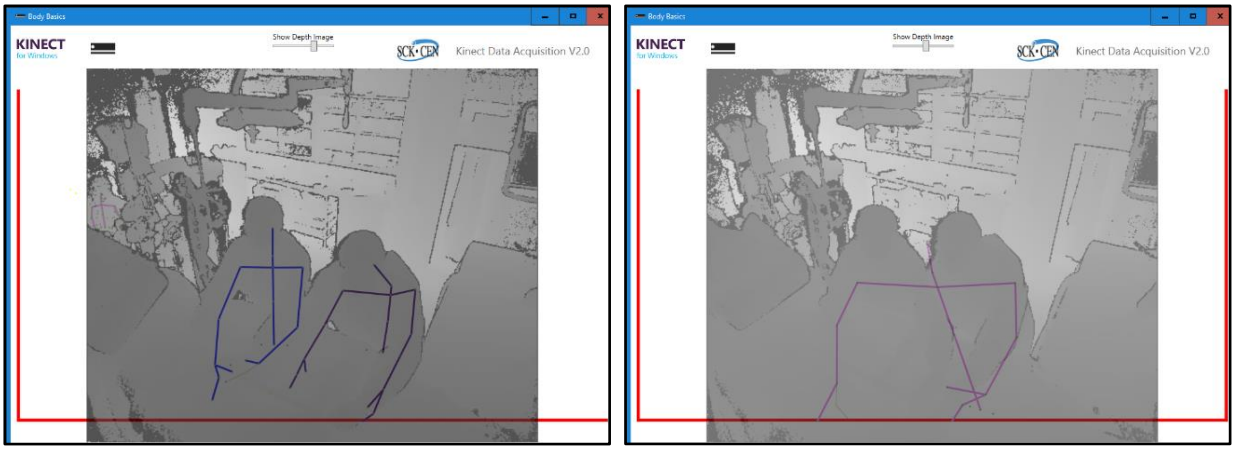


Figure 9. Screenshots of depth-map image showing staff working closely together but with two skeletons tracked correctly (L) and, a short time later, with only one skeleton tracking the two staff members.

The problem of occlusion can not only result in incorrect skeletal representation. The Kinect can also swap the Body ID between two staff members. The Kinect will record any person in the field of view and up to 6 Body ID datasets (no. 0-5) can be created at one time with numbers randomly assigned. That is, if the main operator is first tracked and assigned Body ID=4, it is highly likely that in a busy room with many staff entering and leaving the scene and moving positions around him or her, that they will not remain assigned Body ID=4 for the entire case. This must be considered to ensure the IPS in the end knows the Body ID(s) assigned to the operator during each RDSR event. Changes can also occur during digital acquisition runs, as it is good radiation protection practice for staff to step back from the table as far as possible during these runs which generate relatively high levels of scattered radiation. If they step back, staff may leave the field of view of the Kinect and be assigned a new body ID when they return. The IPS needs a mechanism for accounting for this.

It is evident from the validation that occlusions, staff leaving the scene, staff swapping body ID and disconnections of the tracking camera are a problem. Work will need to continue on a system to ensure that the IPS recognizes the person that was being tracked, i.e. an additional external tracking or face recognition system. This is being developed in WP1. The two-camera system is also intended to solve some of these issues.

It has been shown in report D9.113, that in terms of overall hospital usability, the preliminary results from PODIUM are promising. Taking into account the clinical situation, we have also explored here some of the limitations that may lead to differences between calculations and measurements. The list of recommendations below is intended to provide some guidance on future needs and areas where limitations may be reduced or eliminated.

III. Recommendations for Future Improvements

1. Tracking of the main operator in a reliable and fully automated way, taking into account the real clinical situation (occlusions, staff swapping roles, staff leaving the room) is a key challenge to be addressed.

2. Automated tracking of items such as the ceiling-lead screen and the X-ray C-arm should also be solved.

3. The minimum technical requirements for the X-ray system must be established i.e. an RDSR file in the DICOM standard is a pre-requisite, along with any key exposure parameters that are mandatory in the RDSR for PODIUM.

4. Work should continue with X-ray vendors in terms of links to the existing equipment to gain real-time position and dose information.

5. The minimum technical requirements for the IT solution must be established, along with details on expected file size and storage requirements.

6. The camera and associated equipment should be integrated, discrete, wireless, battery operated, cable free and safe for the clinical environment.

7. A detailed user manual for installation and operation, and a training programme should be developed.

8. Privacy, ethics, data protection and IT security aspects must be clearly established for any future solution with the aim that it will be applicable across all EU member states in terms of GDPR and taking into account any national requirements.

9. The system must be fast, automated and user friendly. The time to manage the system should not exceed current time requirements for managing individual personal dosimetry programmes.

10. The work done by the project partners in WP6 on the legal aspects of seeking approval for PODIUM to be an approved dosimetry service should continue.

IV. Conclusions and future work

The experience gained from the clinical validation measurements has informed the list of recommendations above on future needs. These items are seen as key factors in the future success of a tool such as PODIUM and work should continue to address them and improve this innovative solution. Overall the feedback from the hospital community has been very positive. PODIUM is perceived as an innovative way forward; staff are interested and expect instant results on a website or on their smartphone app. It is envisaged that the availability of individual dose data will increase awareness of radiation dose, improve compliance with radiation protection tools and assist with application of the ALARA principle. It can be seen that the first results from the validation are very promising. There are areas that PODIUM did not perform validation and future work could look at its use in, for example, paediatric settings, other IR procedures, very lengthy cases, and on other vendor systems with different RDSR files. Calculation in real-time during procedures is desirable and this will require a real-time connection with the vendors equipment. Ethics and privacy aspects must continue to be addressed, as if there are barriers, they may prove more difficult to overcome than the technological challenges. The Interventional radiology / cardiology environment is one of the most complex situations for personal dosimetry so it was ambitious yet highly worthwhile to try the proof-of-concept PODIUM approach in this field and it may prove easier to implement in other workplaces. Testing of the complete online tool still remains to be done but it is clear that there is great promise in continuing to develop this type of innovative solution.