# PROJECT FINAL REPORT

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| **Project title:** | | Safety and Efficacy of a New and Emerging Dental X-ray Modality | | |
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**Name, title and organisation of the scientific representative of the project's coordinator:**


Professor Keith Horner
University of Manchester

**Tel:** +44 (0) 161 275 6640

**Fax:** +44 (0) 161 275 6840

**E-mail:** keith.horner@manchester.ac.uk


**Project website address:** http://www.sedentexct.eu/

# 1. Executive Summary

Cone Beam Computed Tomography (CBCT) has been available to dentists for only around ten years. It provides cross-sectional imaging, but at a higher radiation dose than conventional dental radiography. The latter is particularly important in dentistry, where treatment of children forms a large part of clinical work. A large variety of CBCT equipment is on the market and use of CBCT is proliferating. Research to establish the clinical role of CBCT has lagged behind its growth. Evidence-based guidelines on diagnostic usefulness, radiation doses, quality assurance and economic aspects were unavailable, while the educational needs of users was also unaddressed at the start of the project. The overriding aim of the SEDENTEXCT project was, therefore, to acquire key information necessary for sound and scientifically based clinical use of CBCT. In order that safety and efficacy are assured and enhanced in the 'real world', the parallel aim was to use the information to develop evidence-based guidelines dealing with justification, optimisation and referral criteria and to provide a means of dissemination and training for users of CBCT.

The project undertook the most extensive survey of dental CBCT radiation doses ever performed, including paediatric dosimetry. This showed a wide range of doses from different equipment, demonstrating the scope for optimising doses, but with a clear trend towards lower doses when the size of the scan field was limited. Dosimetry work is time-consuming when faced with new CBCT models and manufacturer upgrades and the project addressed this by developing mathematical methods of calculating dose. Work relevant to staff safety was also performed by measuring scatter dose around CBCT machines. Quality assurance is a key part of radiation protection but requires suitable test tools and a testing protocol. In the project, a commercially available quality control phantom and software were developed and a quality control programme for dental CBCT devised. The diagnostic usefulness of dental CBCT was investigated for a set of key clinical uses. The results of these are notable in that they do not give wholehearted support for the value of CBCT; instead, they suggest that clinical use should be highly selected. The availability of CBCT improves the surgeon's confidence, but does not necessarily lead to better diagnosis or changes in treatment. Few diagnostic imaging methods have undergone any formal economic evaluation, but the project performed this for CBCT and established a methodology which can be used by others in the future. Dental CBCT is substantially more expensive than conventional radiography, but costs vary widely, depending on the healthcare context.

The training needs of CBCT "stakeholders" (dentists, radiologists, medical physicists, manufacturers, the public) was investigated using online consultations and ranked lists of needs were established. A curriculum and learning outcomes were developed and an online Training Programme produced, based upon recorded lectures, a Wiki and additional learning materials. A focus of the project was the development of evidence-based guidelines for dental CBCT. As a first step, consensus methods were used amongst key stakeholders to establish "Basic Principles" of CBCT use. Systematic review and a strict methodology were then used to construct a Provisional Guideline document which was disseminated widely. This was developed further to incorporate the results of the other parts of the project and a Definitive Guideline document produced. Dissemination of this will continue beyond the duration of the project and will be its most enduring legacy.

# 2. Project Context and Objectives

## 2.1 Project context

The context of the project was the proliferation of a new X-ray imaging technique for clinical dentistry in the absence of research evidence for safety and efficacy. Examination of the literature when planning this project demonstrated that current knowledge was insufficient to allow development of comprehensive guidance on justifiable clinical use, procedures for keeping radiation doses to a minimum, and quality assurance methods for CBCT in dentistry. Relatively recent European Guidelines on Radiation Protection in Dental Radiology (European Commission, 2004) had not included reference to CBCT, underlining the rapid development and introduction of CBCT into clinical practice. Information and guidelines for CBCT are particularly important in dental X-ray imaging because:

a) dental radiology is largely performed in primary care, outside hospitals and their associated radiation protection structure,
b) CBCT doses are substantially greater than those associated with conventional dental imaging techniques,
c) dental radiology is predominantly performed on younger patients, for whom radiation risk is highest.

In addition to these aspects, the training needs of users of CBCT (dentists, radiologists, medical physicists, manufacturers and sales personnel, the public) had not been addressed.

The principle of 'Justification' is a central pillar of radiation protection. Any x-ray exposure should show a net benefit to the patient, weighing the total potential diagnostic benefits it produces against the individual harm that the exposure might cause. The efficacy, benefits and risk of available alternative techniques having the same objective but involving no or less exposure to x-rays should be taken into account. In dentistry, this issue was addressed specifically by the 2004 European Guidelines on Radiation Protection in Dental Radiology. This document included some evidence-based guidelines for the common dental radiological procedures, largely derived from a previous document developed in the UK. Unfortunately, these guidelines did not include reference to CBCT. This lack of guidelines had also been raised as a potential concern with CBCT in the United States. Review of the scientific literature showed an enthusiasm for use of CBCT by individuals based on subjective opinion. There was a real risk that CBCT would be perceived by dentists as a panacea for all ills, leading to excessive use as seen with conventional ("medical") CT. Beyond clinical effectiveness, safe use of CBCT needs guidelines on keeping doses low while maintaining good quality images, staff safety and quality assurance. Before the start of this project, no such guidelines were available and CBCT users were working in isolation without a "good practice framework".

It is fundamental to radiation protection that the benefits of a procedure using ionizing radiation outweigh the risks; this is incorporated into the relevant European Directive 97/43/Euratom. At the start of this project, the limited studies in the literature indicated that the patient radiation dose achievable with dental CBCT units was substantially less than conventional ("medical") CT but higher than conventional dental radiography. More work was needed to verify this limited literature on radiation doses for a greater range of current CBCT systems and without the inter-study variation in measurement methodologies. Furthermore, there were no extensive reports available regarding the personnel dose for users of CBCT equipment. There were no clear guidelines regarding the proper installation of CBCT devices into dental practices or hospitals to limit the dose to the environment.

The Quality Assurance (QA) process is vital in order to provide confidence in the suitability of an imaging technique for its intended purpose and to ensure its safe clinical use. It is usually performed by using a test "phantom" in conjunction with software routines that help in the interpretation of the results. The phantom, constructed of materials of known characteristics, essentially acts as a "standard patient", allowing repeated x-ray exposures to be performed and image quality measured. Preliminary tests before the start of this project on a dental CBCT unit showed that using a phantom designed for QA of medical CT equipment resulted in images with worse resolution than the medical CT scan. Furthermore, discrimination between objects with different density was not always successful. It was speculated that this was due to the fact that dental CBCT units are optimized for imaging of hard tissues, i.e. bone. This is also related to the relatively low dose delivered compared with medical CT. Therefore, the development of a specifically designed phantom, with a size and densities resembling those of dental interest was necessary, including special software tools for the interpretation of the results and the evaluation of image quality.

There are a multitude of diagnostic applications of radiology in dentistry. The existing literature on CBCT was considerably diluted by numerous non-systematic reviews and single case reports. Such opinion-led papers, invariably enthusiastic in their support for using CBCT, added little to our knowledge of diagnostic usefulness. Radiology for orthodontics is a key clinical application for CBCT. Most orthodontic treatments are performed in the first or second decades of life, when radiation-related risk is highest. Concerns over the use of x-rays in orthodontic treatments was highlighted in the European Guidelines on Radiation Protection in Dental Radiology (European Commission, 2004), emphasising the need for careful clinical assessment prior to selecting the need for x-ray imaging. Many patients do not require complex imaging for orthodontic treatment planning and some no imaging at all. This European Commission document included indications for X-ray of patients for orthodontic treatment but did not consider CBCT as, at that time, there was extremely limited literature available on CBCT use in orthodontics. Preliminary review of the literature by the applicants shows that this literature was dominated by anecdotal reports and 'reviews'. Similar criticisms could be addressed at publications suggesting the usefulness of CBCT for a range of dental applications, including dental caries (decay), bone health around teeth, jaw joint problems and various minor surgical procedures including wisdom tooth assessment. Some of these studies also failed to demonstrate good research design.

Before accepting a new method for clinical diagnosis in dentistry, evidence should be available that the new method does more good than harm. This is particularly important with X-ray based methods. It should also be checked whether the costs for the new method are reasonable. Economic evaluation attempts to weigh effects and costs of alternative methods with the goal that available resources are used to achieve maximum benefits for patients in terms of health and quality of life. In emerging technologies, this is particularly important to avoid inappropriate and excessive use. Before the start of the project, dental CBCT was an emerging technology and no studies had been performed that reported how examination with CBCT benefits the patient and how much an examination actually costs compared with traditional radiological examinations, for different dental problems.

There was very little education and training of general dentists about CBCT before the project started. What was available was provided by manufacturers, who have a vested interest in portraying their equipment, and its capabilities, in the best light. CBCT was not covered as part of the undergraduate dental curriculum. CBCT equipment was reducing in price, resulting in the possibility of ordinary "high street" dentists purchasing this equipment for their practices. Even where the equipment was not immediately available to a dentist in his practice, referral to a specialist centre required him/her to interpret the CBCT image and report the findings to a patient. Clearly, this situation was not favourable to good patient care.

## 2.2 Project objectives

*Work package 1: Justification and Guideline Development*

The overall aim of this work package was to develop guidelines on referral criteria for CBCT, quality assurance and optimisation of CBCT use. The specific objectives were:

- to perform a systematic review of CBCT based on ‘dose and risk’, ‘diagnostic accuracy’ and ‘quality assurance’
- to develop provisional guidelines
- to incorporate knowledge gained from other parts of the SEDENTEXCT project
- to develop definitive referral criteria and guidelines on quality assurance and optimisation

*Work package 2: Dosimetry*

The overall aim of this work package is to determine the level of (1) patient dose in dental CBCT, paying special attention to paediatric dosimetry, and (2) personnel dose in dental CBCT. These goals corresponded to the following sub-objectives:

- The development of a standardised technical dose index to characterise dose distribution in CBCTs
- The estimation of the effective dose in anatomical phantoms
- *In vivo* skin dose measurements
- The development of mathematical models for dental CBCT dosimetry
- Measurements of the scatter dose around scanners and to explore the consequences for radiation protection of personnel and helpers

*Work package 3: Optimisation*

The overall aim of Work package 3 was to produce tools (phantom and software) and a protocol to assist in periodic quality assurance (QA) testing. The specific objectives were:

- to develop, design and test a phantom for QA tests on dental CBCT equipment
- to develop software tools for the evaluation of image quality and for routine QA testing
- to form and implement a routine QA protocol, for periodic QA tests in daily clinical practice
- to form an Image Quality testing protocol and determine its implementation on CBCT units.

*Work package 4: Diagnostic accuracy*

The overall aim of Work package 4 was to answer the questions:

- What additional information does CBCT exams provide compared with clinical and two-dimensional radiological methods?
- What is the accuracy of such CBCT information?
- Would any of the additional information on three dimensions change the treatment in an essential way?

To answer these questions, various *in vitro* and clinical studies, often observer-based, were performed, the objectives being:

1. To determine the segmentation, linear and diagnostic accuracy of CBCT, using various scanners *in vitro*
2. To determine diagnostic accuracy for CBCT for specific clinical applications: implant placement, impacted teeth (canines and 3rd molars) and maxillary sinus grafting procedures in relation to dental implant planning.

*Work package 5: Cost effectiveness*

The goal of Work package 5 was to analyse the cost-effectiveness of CBCT in different clinical situations, health care contexts and countries. The specific objectives were:

- To analyse how much examinations with CBCT cost both the health care provider and the patient for different clinical problems in dentistry, compared with the costs of conventional radiological methods
- To analyse any differences in costs of CBCT between the centres participating in the study
- To analyse how access to CBCT radiographs influence the decisions of radiologists and the clinicians who are treating the patient

*Work package 6: Training and valorisation*

The overall aim of Work package 6 was to develop a website providing information resources and training materials on CBCT, for use by dental professionals, medical physicists and others interested in CBCT, e.g. students, equipment manufacturers and the general public. The specific objectives were:

- to perform a needs analysis amongst the professional community to inform the design of the website and its content
- to provide a robust and cost-effective means of delivery of on-line training and information dissemination
- to provide an open repository of knowledge and experience on CBCT, including the Guidelines developed by Work package 1
- to ensure continued support and maintenance of the resources developed in the Work package beyond the lifetime of the project

# 3. Main Scientific and Technical Results / Foregrounds

## 3.1 Work package 1: Justification and Guideline Development

### 3.1.1 Initial work

The first step in this Work package (WP1) was to assemble a multidisciplinary group of experts and to form a "Guideline Development Panel" (referred to as the "Panel" hereafter). The project partners included individuals with a wide range of backgrounds, including dentists, dental specialists including dental radiologists, medical physicists and scientists with a special interest in CBCT. An expert in evidence-based dentistry, with experience of clinical guideline development, was also available. The Panel membership was agreed at the first project meeting. Through a consensus process, the scope of the guidelines was discussed and agreed. The following key topic areas were initially identified:

- Diagnostic accuracy studies
- Radiation dose and Risk
- Optimisation of radiation dose for patients and staff
- Quality standards/assurance
- Cost/Benefit Analysis
- CBCT use

According to the project plan, the guideline development process was to be built upon *systematic review* of the scientific literature, incorporating any available national or specialist guidelines. Systematic review is focused on a research question that tries to identify, appraise, select and synthesize all high quality research evidence relevant to that question. By following this approach, the influence of bias and opinion can be minimized. As a first step, a search strategy was developed (Table 1). A "search strategy" is a way of interrogating computerized databases to extract relevant information from the mass of scientific publications which form the broad scientific literature.

***Table 1**: Search strategy developed for Medline (OVID)*

| Search terms | |
|---|---|
| 1 | cone beam computed tomography.mp. |
| 2 | volumetric radiography.mp. |
| 3 | volumetric tomography.mp. |
| 4 | digital volumetric tomography.mp. |
| 5 | digital volume tomography.mp. |
| 6 | Cone-beam.mp. or exp Cone-Beam Computed Tomography/ |
| 7 | (volume ct or volumetric ct).mp. |
| 8 | (volume computed tomography or volumetric computed tomography).mp. |
| 9 | (cbct or qcbct).mp. |
| 10 | or/1-9 |
| 11 | (dental or dentistry).mp. |
| 12 | exp dentistry/ |
| 13 | (intra-oral or intraoral).mp. [title, original title, abstract, name of substance word, subject heading word] |
| 14 | oral surgery.mp. or exp surgery, oral/ |
| 15 | endodontics$.mp. or exp endodontics/ |
| 16 | orthodontics$.mp. or exp orthodontics/ |
| 17 | (periodontic$ or periodontology).mp. or exp periodontics/ |

| | |
|---|---|
| 18 | exp dental caries/ |
| 19 | maxillofacial.mp. |
| 20 | or/11-19 |
| 21 | 10 and 20 |

The following databases were searched:

- MEDLINE (OVID) (1950 onwards)
- EMBASE (OVID) (1980 onwards)
- Web of Science
- Scopus
- UK Clinical Research Network
- Clinical Trials.gov
- Register of Controlled Trials (www.controlled-trials.com)
- NICE guidelines (www.nice.org.uk)
- FDI World Dental Federation Guidelines (www.fdiworldental.org).

### 3.1.2 Basic Principles of the use of Dental CBCT

Early in 2008, it became apparent that there was an urgent need to provide some basic guidance to users of dental CBCT because of concerns over inappropriate use. These concerns were voiced by the European Academy of DentoMaxilloFacial Radiology (EADMFR), an organisation whose objective is to promote, advance and improve clinical practice, education and/or research specifically related to the specialty of dental and maxillofacial radiology within Europe. EADMFR has a membership exceeding 300 individuals whose special interest is imaging of the dental and maxillofacial region. It is multi-disciplinary, including dental radiologists, medical physicists, radiographers and scientists. It includes both academics (teachers and researchers) and clinicians. In view of the mutual aims of EADMFR and SEDENTEXCT, a decision was taken to collaborate in the development of a set of "Basic Principles" for the use of dental CBCT, based upon existing standards. These standards include fundamental international principles, EU Directives and previous Guidelines.

A set of 20 "Basic Principles" on the use of dental CBCT was established using a consensus process (Horner et al, 2009). Consensus is an organised method to achieve agreement of the majority with mitigation of minority views, avoiding a "top/down" approach. Draft statements were developed by a small team of collaborators but then discussed and adapted in a large EADMFR meeting held in Budapest in 2008. The final draft questions were then presented to the EADMFR members for scoring using an online questionnaire, to which members were directed by email. Consensus was achieved and the Principles (Table 2) were published, describing the minimum requirements for using CBCT.

***Table 2**: The "Basic Principles" on the use of Cone Beam CT, established by consensus of members of the European Academy of Dental and Maxillofacial Radiology (Horner et al, 2009).*

| | |
|---|---|
| 1 | CBCT examinations must not be carried out unless a history and clinical examination have been performed |
| 2 | CBCT examinations must be justified for each patient to demonstrate that the benefits outweigh the risks |
| 3 | CBCT examinations should potentially add new information to aid the patient's management |
| 4 | CBCT should not be repeated 'routinely' on a patient without a new risk/benefit assessment having been performed |
| 5 | When accepting referrals from other dentists for CBCT examinations, the referring dentist must supply sufficient clinical information (results of a history and examination) to allow the CBCT Practitioner to perform the Justification process |
| 6 | CBCT should only be used when the question for which imaging is required cannot be |

| | |
|---|---|
| | answered adequately by conventional (traditional) radiography |
| 7 | CBCT images must undergo a thorough clinical evaluation (‘radiological report’) of the entire image dataset |
| 8 | Where it is likely that evaluation of soft tissues will be required as part of the patient’s radiological assessment, the appropriate imaging should be conventional medical CT or MR, rather than CBCT |
| 9 | CBCT equipment should offer a choice of volume sizes and examinations must use the smallest that is compatible with the clinical situation if this provides less radiation dose to the patient |
| 10 | Where CBCT equipment offers a choice of resolution, the resolution compatible with adequate diagnosis and the lowest achievable dose should be used |
| 11 | A quality assurance programme must be established and implemented for each CBCT facility, including equipment, techniques and quality control procedures |
| 12 | Aids to accurate positioning (light beam markers) must always be used |
| 13 | All new installations of CBCT equipment should undergo a critical examination and detailed acceptance tests before use to ensure that radiation protection for staff, members of the public and patient are optimal |
| 14 | CBCT equipment should undergo regular routine tests to ensure that radiation protection, for both practice/facility users and patients, has not significantly deteriorated |
| 15 | For staff protection from CBCT equipment, the guidelines detailed in Section 6 of the European Commission document *‘Radiation Protection 136. European Guidelines on Radiation Protection in Dental Radiology’* should be followed |
| 16 | All those involved with CBCT must have received adequate theoretical and practical training for the purpose of radiological practices and relevant competence in radiation protection |
| 17 | Continuing education and training after qualification are required, particularly when new CBCT equipment or techniques are adopted |
| 18 | Dentists responsible for CBCT facilities who have not previously received ‘adequate theoretical and practical training’ should undergo a period of additional theoretical and practical training that has been validated by an academic institution (University or equivalent). Where national specialist qualifications in DMFR exist, the design and delivery of CBCT training programmes should involve a DMF Radiologist |
| 19 | For dento-alveolar CBCT images of the teeth, their supporting structures, the mandible and the maxilla up to the floor of the nose (eg 8cm x 8cm or smaller fields of view), clinical evaluation (*‘radiological report’*) should be made by a specially trained DMF Radiologist or, where this is impracticable, an adequately trained general dental practitioner |
| 20 | For non-dento-alveolar small fields of view (e.g. temporal bone) and all craniofacial CBCT images (fields of view extending beyond the teeth, their supporting structures, the mandible, including the TMJ, and the maxilla up to the floor of the nose), clinical evaluation (*‘radiological report’*) should be made by a specially trained DMF Radiologist or by a Clinical Radiologist (Medical Radiologist) |

### 3.1.3 Provisional Guidelines on CBCT

Following the project work plan, the intention was to produce Provisional Guidelines at an early stage in the project and an updated and comprehensive set of “Definitive” guidelines close to the end of the project.

Using the search strategy described in Section 3.1.1, relevant literature was identified and distributed to Panel members for appraisal and grading, using standard proformas for collection of data. The results from the assessment of all identified articles were tabulated to produce ‘Evidence Tables’. A meeting of members of the GDP was held to discuss the Evidence Tables and to formulate and grade provisional recommendations. When producing the provisional recommendations, members of the GDP were asked to consider:

- Volume of evidence
- Applicability of the findings to clinical practice
- Generalisibility of the results presented to the guideline’s target population

- Consistency of the results (highlight any major inconsistencies)
- Clinical impact (e.g resource implications, balance of risk/benefit)

Each provisional recommendation was linked, where applicable, to the relevant research evidence. It was graded according to an adaptation of the SIGN grading system (Table 3).

***Table 3:*** *Grading systems used for levels of evidence [adapted from Scottish Intercollegiate Guidelines Network (SIGN), 2008].*

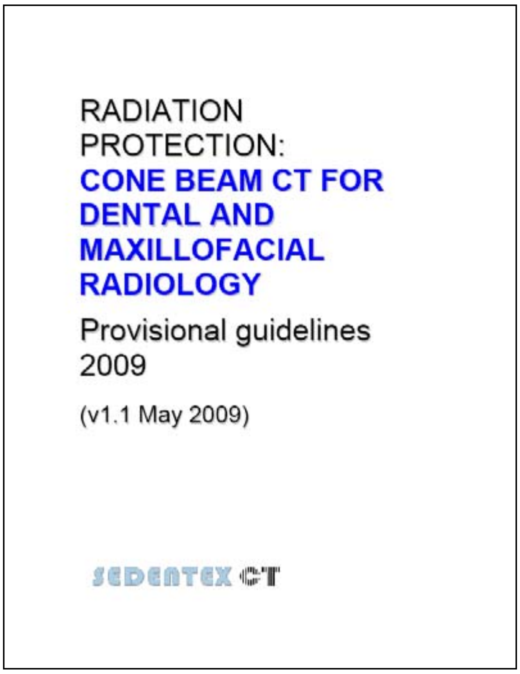
| Grade | |
|---|---|
| **A** | At least one meta analysis, systematic review, or RCT rated as 1++, and directly applicable to the target population; or a systematic review of RCTs or a body of evidence consisting principally of studies rated as 1+, directly applicable to the target population, and demonstrating overall consistency of results |
| **B** | A body of evidence including studies rated as 2++, directly applicable to the target population, and demonstrating overall consistency of results; or extrapolated evidence from studies rated as 1++ or 1+ |
| **C** | A body of evidence including studies rated as 2+, directly applicable to the target population and demonstrating overall consistency of results; or extrapolated evidence from studies rated as 2++ |
| **D** | Evidence level 3 or 4; or extrapolated evidence from studies rated as 2+ |
| **GP** | Good Practice (based on clinical expertise of the guideline group) |

Two additional gradings were used:

- A grade of “**ED**” was applied where a statement was directly derived from The Council of the European Union Directive 96/29/Euratom of 13 May 1996 (laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiation) or Council Directive 97/43/Euratom of 30 June 1997 (on health protection of individuals against the dangers of ionizing radiation in relation to medical exposure).
- A grade of “**BP**” was applied where a statement was identical to, or directly derived from, a “Basic Principle” of use of dental CBCT (3.1.2).

The Panel developed 53 recommendation statements, of which 34 were related to clinical uses of CBCT (referral criteria). The evidence grades were generally low, reflecting the limited evidence available on which to base recommendations. The guideline development process was completed by the production of *“Radiation Protection: Cone Beam CT for Dental and Maxillofacial Radiology. Provisional Guidelines” (v1.1)* in May 2009 (Figure 1). This was published on the project website (www.sedentexct.eu) and also distributed widely to international and national professional organisations and societies. Specialist online newsgroups and newsletters were also used as means of dissemination. A press release was also used as a way of increasing publicity.

***Figure 1**: Cover page of "Radiation Protection: Cone Beam CT for Dental and Maxillofacial Radiology. Provisional Guidelines". Produced by the SEDENTEXCT project in May 2009.*


RADIATION PROTECTION:
**CONE BEAM CT FOR DENTAL AND MAXILLOFACIAL RADIOLOGY**
Provisional guidelines 2009
(v1.1 May 2009)
SEDENTEX CT

3.1.4 Definitive Guidelines

Following the completion of the Provisional Guidelines, the work plan was aimed at development of a "definitive" set of Guidelines which would incorporate the rapidly accumulating literature on CBCT and, specifically, the output from the other Work packages in the SEDENTEXCT project.

The methodology used was broadly the same as that used for development of the Provisional Guidelines, with on-going systematic review, critical appraisal and recommendation development with evidence grading. In addition to the identified literature, the Panel identified national guideline documents on CBCT which had been produced since 2009. Seven such national documents were identified (from Belgium, Denmark, France, Germany, Norway and two from the UK). It was noted that most of these included reference to, and inspiration from, the "Basic Principles" and Provisional Guideline documents produced by the SEDENTEXCT project.

The Panel met in November 2010 and in March 2011 to consider aspects of the revision of the Provisional Guideline document. Evidence Tables were considered, along with copies of the original papers if required, and the provisional recommendations from 2009 reviewed and revised as necessary. When producing the Definitive Guidelines, members of the Panel were asked to consider:

- Volume of evidence
- Applicability of the findings to clinical practice
- Generalisibility of the results presented to the guideline's target population
- Consistency of the results (highlighting any major inconsistencies)
- Clinical impact (e.g resource implications, balance of risk/benefit)

Each guideline statement was linked, where applicable, to the relevant research evidence. It was graded according to an adaptation of the SIGN grading system (Table 3). To aid in the development of clinical referral criteria, GDPs were asked to consider two questions:

- Is CBCT indicated as a *standard* method for clinical use for this application?
- Is CBCT indicated for *selected* clinical use for this application?

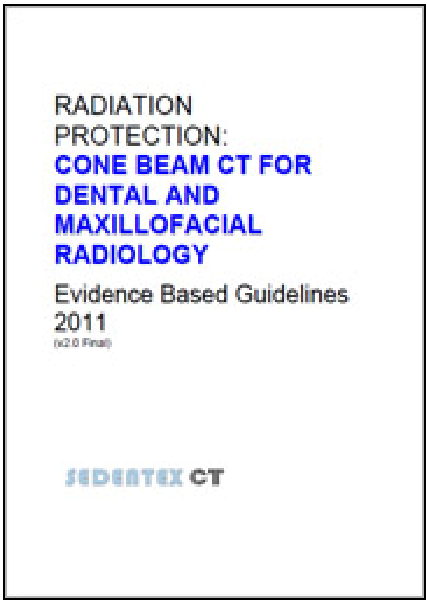
A set of 68 recommendations were developed by the Panel, of which 43 were referral criteria. The document includes recommendations for future research and development and a comprehensive Quality Control Manual for CBCT systems (see 3.3, below). Examples of recommendations are shown in Table 4.

Draft Definitive Guidelines (v1.0) were produced which underwent internal peer review within the project and assessment by independent external reviewers to produce the Definitive Guidelines v1.1. These were considered by further external reviewers and by members of the EADMFR. The latter completed an on-line consensus survey process to consider the guidelines rated 'best practice'. Following further revision, the final SEDENTEXCT Definitive Guidelines (v2.0) were released on 24 May 2011 (Figure 2).

***Table 4**: Example Guideline statements taken from "Radiation Protection: Cone Beam CT for Dental and Maxillofacial Radiology. Evidence-based Guidelines". Produced by the SEDENTEXCT project in May 2011.*

| Guideline statement | Grade |
|---|---|
| *Limited volume, high resolution CBCT may be indicated in selected cases of infra-bony defects and furcation lesions, where clinical and conventional radiographic examinations do not provide the information needed for management.* | C |
| *Kilovoltage and mAs should be adjustable on CBCT equipment and must be optimised during use according to the clinical purpose of the examination, ideally by setting protocols with the input of a medical physics expert.* | B |
| *As a minimum target, no greater than 5% of CBCT examinations should be classified as "unacceptable". The aim should be to reduce the proportion of unacceptable examinations by 50% in each successive audit cycle.* | GP |

***Figure 2**: Cover page of "Radiation Protection: Cone Beam CT for Dental and Maxillofacial Radiology. Evidence-based Guidelines". Produced by the SEDENTEXCT project in May 2011.*



The content of the Guidelines was divided into the following:

- Radiation dose and risk
- Basic Principles of CBCT use
- Justification and referral criteria
- CBCT equipment factors in the reduction of radiation risk to patients
- Quality standards and quality assurance
- Staff protection
- Economic evaluation
- Training

To this were added four appendices:
Appendix 1 Summary of recommendations
Appendix 2 Recommendations for research and development
Appendix 3 Glossary and abbreviations
Appendix 4 Quality Control Manual for dental CBCT systems

In summary, the guidelines highlight the fact that the radiation dose and risk from dental CBCT are generally higher than conventional radiography undertaken by the dentist, but lower than for CT. Clear guidance on optimising doses for patients were included. CBCT machines should offer a variety of settings, and examinations should be undertaken using those settings which are compatible with the clinical situation whilst providing the lowest achievable dose.

It was shown that CBCT has been used for a wide variety of clinical situations within dentistry, such as identifying the position of unerupted teeth, assessment of cleft lip and palate, diagnosis of caries, the effects of gum disease and trauma. Research evidence suggests that CBCT is only indicated for certain situations, particularly those where CT is the current imaging method of choice or when the question for which imaging is required cannot be answered adequately by lower dose conventional (traditional) radiography.

The Guidelines highlighted that it is essential that a qualified expert is consulted over the installation and use of CBCT to ensure that staff dose is as low as reasonably achievable and that all relevant national requirements are met. A quality assurance programme should be followed to ensure consistently adequate diagnostic information, while radiation doses are controlled to be as low as reasonably achievable.

A written record of this programme should be maintained by staff to ensure adherence to the programme and to raise its importance among staff. In addition, assessment of the clinical images and other clinical audit should be undertaken on a regular basis to confirm that the equipment is being used correctly to produce clinically useful images.

Further information on the Quality Control manual is given in Section 3.3 below.

No set of guidelines is permanent. In the context of a rapidly growing new technology like dental CBCT, the need for review and development is even more important. This is particularly needed for referral criteria. The first formal statement in the Guideline document was, therefore, to recommend that the Guidelines are reviewed after a period no longer than five years after its publication.

## 3.2 Work package 2: Dosimetry

Radiation "dose" is a measure of the energy imparted to the patient (or other person exposed, such as a worker) when exposed to X-rays or other form of ionising radiation. An accurate understanding of the doses involved in dental CBCT is of fundamental importance in planning radiation protection measures. “Dose” can be defined in several ways; the *absorbed dose* for an organ is defined by the amount of energy delivered to that organ per unit of mass (measured in joules/kg, with the latter unit being renamed a *gray*, Gy). In clinical radiology, however, we are concerned a lot about the risks and how we can quantify them. The measurement of dose that can be related to risk is called *“effective dose”*. This standardises measured organ doses by adjusting values to take into account the type of ionising radiation (in this case X-rays) and the organs and tissues exposed during a procedure. The latter is important because different tissues have different sensitivities to X-rays. Thus, the same X-ray “exposure” (same exposure time, current and voltage, field size) can carry different risks depending on the part of the body irradiated. Different tissues and organs have been allocated radiosensitivity weighting values that are used in calculating effective dose. The organs relative to dental work include the thyroid gland, the salivary glands, the brain and bone marrow. A radiosensitivity value is also allocated to the “remainder organs” i.e. other tissues and organs which have no specific allocated weighting value. Effective dose is also measured in joules/kg, but to differentiate it from other measurements of “dose”, another unit name is used, the *sievert* (Sv). The sievert is a very large unit, so in practice we more usefully express effective dose as thousandths or millionths of sieverts (mSv and μSv, respectively). The effective dose can be numerically related to risk from X-ray exposure. A final point is that the age of the person being X-rayed is important to risk, with younger patients having a risk two to three times as great as an adult.

In this Work package, the research covered several aspects of dosimetry. The results of these studies are described in Sections 3.2.1 to 3.2.5 below.

### 3.2.1 Development of a standardised dose index to characterise dose distribution in CBCTs

A “dose index” is a commonly used radiation exposure index to give a quick representative estimate of patient radiation risk. It gives a standardised measurement and is reported by manufacturers and by medical physicists undertaking equipment testing. For conventional (medical) CT, the Computed Tomography Dose index (CTDI) is well established and widely used. The aim of this work was to attempt to develop a comparable Dose index for CBCT which could fill the same role as CTDI.

Our aim was to characterise the distribution of radiation dose in a standard “phantom” (as a patient substitute) for a range of CBCT units, investigating different exposure conditions. The implications of the dose distributions on the definition and practicality of a dose index were assessed. The implications of the dose distributions on the definition and practicality of a CBCT dose index were assessed.

It was found that the dose distribution in dental CBCT is not so simple as for CT. For example, dose distribution can be asymmetrical due to variable exposure geometries such as “off-axis positioning” of the field of view (FOV: the size of the volume that is reconstructed by the CBCT device), or a scan with a partial rotation. The consequences of this are significant. If two scans are taken using the same exposure parameters, but the centring point is changed, so will the dose distribution. Based on the dose distribution measurements, different possible dose indices were proposed, as there is no optimal solution due to the complicated CBCT dose distribution and practical aspects of a quality control protocol. However, the proposed indices all provide an estimation of the dose which is deposited throughout a head-sized volume, and can be implemented into practice if the appropriate equipment (phantom & dosimeter) are available.

The indices were measured in practice, and linked to the Monte Carlo dose simulations (see Section 3.2.4 below) to establish conversion factors.

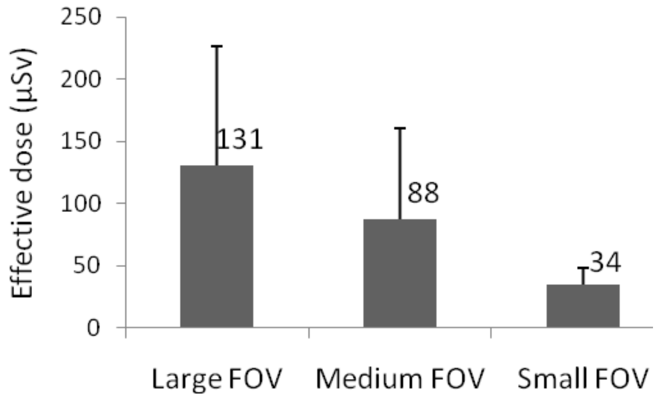
### 3.2.2 Measurement of the dose distribution in anatomical phantoms and subsequent calculation of effective dose

An adult phantom was used for these measurements, as well as two (10 year old and adolescent) paediatric phantoms. For the adult phantom, the effective dose for different CBCT devices showed a 20-fold range (19-368 µSv). The largest contributions to the effective dose were from the remainder tissues (37%), salivary glands (24%), and thyroid gland (21%). For all organs, there was a wide range of measured values apparent, due to differences in exposure factors and in diameter, height and positioning of the FOV relative to the radiosensitive organs.

For the 10 year old and adolescent phantom, average effective doses were 116 µSv and 79 µSv respectively which are comparable to adult doses. Similar to the adult phantom, a wide range in effective dose was observed. There was a fourfold increase in the thyroid dose of the 10 year old compared with the adolescent because of its smaller size. The remainder tissues, salivary and thyroid glands contributed the most to the effective dose for a 10 year old while for an adolescent, the remainder tissues and the salivary glands contributed the most.

The results show that a distinction is needed between small-, medium-, and large-field CBCT scanners and protocols, as they are applied to different groups of patients, because the dose received is strongly related to FOV size (Figure 3). Furthermore, the dose should always be considered relative to the image quality, seeing that image quality requirements also differ for patient groups. The results from the current study indicate that the optimisation of dose should be performed by an appropriate selection of exposure parameters and FOV size, depending on the diagnostic requirements. Furthermore, it was concluded that it is imperative that dental CBCT examinations on children should be fully justified over conventional X-ray imaging and that dose optimisation by FOV size restriction is particularly important in young children.

***Figure 3:*** *Average effective dose for CBCT devices, divided into groups based on field of view size. Standard deviations are shown for each group. "FOV" means "Field of View", i.e. the total volume of the patient which is imaged. The trend for higher doses with larger FOVs is evident.*




### 3.2.3 In vivo dose measurements

In addition to phantom dose measurements, skin dose measurements were undertaken for different scanner types. The skin dose measurements were done in adults and children, using different clinical indications.

A total of 248 patients were included in this study, encompassing six CBCT devices and a large number of exposure protocols, based on the clinical indication. A wide range of skin dose results was seen, due to patient factors (size and constitution) and scanning factors (FOV size and position, beam quality, amount of exposure).

These results aid in the establishment of diagnostic reference levels for dental CBCT, and provide further evidence that dose limitation is crucial for child patients, and that the amount of exposure should not be fixed but based on patient size.

### 3.2.4 Development of mathematical models for dental CBCT dosimetry

Performing dosimetry in patients is labour-intensive and costly. Computer programmes are available, however, which "model" the distribution of radiation as it passes through material. It is possible to use this to model what happens to the X-rays passing through a patient during a particular X-ray examination and to calculate dose without involving real patients. One computer method which is widely used in radiology (and for other comparable situations in science) is the Monte Carlo simulation method.

A large number of CBCT devices and phantoms were modelled on a validated Monte Carlo framework, and conversion factors were determined to obtain the effective dose from these simulations. Furthermore, the relationship between these simulated effective doses and the measured dose indices was investigated.

The conversion factors (mSv/mAs) from mAs to effective dose for an adult and child computational phantom were calculated for a range of dental CBCT machines and clinical examinations. The error in the computational models was quantified in two stages and it was found to be less than 17%. The conversion factors increase as the irradiated volume increases due to the higher amount of scattered radiation. In addition, the conversion factors increase at higher tube voltages for the same filtration.

The conversion factors for small FOVs were calculated for different examination protocols, for example, mandibular and maxillary wisdom teeth. The conversion factors verify the general trend that was found with the phantom dose measurements, that the closer the isocentre (*i.e.* the centre of rotation of X-ray tube and detector, also the central point of the FOV) is to the salivary glands and thyroid, the higher are the dose and the conversion factors.

The relationship between the conversion factors and the two dose indices was investigated for the two computational phantoms. A linear relationship between the logarithms of the dose indices and the logarithms of the conversion factors was found with dose index 2 giving a better fit than dose index 1 for both phantoms. The fitted equations could be used to derive the conversion factors from the dose indices.

It should be noted that the relationships between the dose index and the conversion factors are empirical and further work should be done using the Monte Carlo simulations and additional dose index measurements to investigate the physical principles behind the relationships. Further work should be done on a range of machines to investigate whether these relationships are machine specific.

### 3.2.5 Measurements of scatter dose and radiation protection of personnel and helpers

When X-rays pass through material, some pass through unhindered, some are absorbed completely while others are scattered. Scattered radiation can expose other parts of the body of the patient to radiation but, of special interest here, can expose other people in the immediate environment, such as operators and patient helpers. It is important to know about scatter for CBCT so that evidence-based guidelines on staff protection can be used.

Scatter dose measurements were performed on ten different models of CBCT devices. The measurements were collected using two techniques: one "active" where a scattering material was placed in the CBCT and a radiation detector positioned at various locations in the room to measure during the exposure; the other “passive” where small dosimeters were attached to walls around the CBCT for a period of 3 to 12 weeks while normal, clinical and non-clinical, exposures were carried. The active measurements, which used the maximum exposure parameters, found that scatter dose per scan at a distance of 1 m from the isocentre of the CBCT was in the range 4.1 – 46.8 μSv (mean: 11.3 μSv, median: 7.4 μSv). The passive measurements, carried out on four models of CBCT, ranged from 2.0 μSv to 8.1 μSv per scan at 1 m.

Information was also gathered on the average number of patients seen in different CBCT facilities and the national requirements or guidelines on the design of such facilities with respect to radiation protection. Example calculations of the shielding requirements, combining all the data, were offered and recommendations based on the measurements were proposed. These results were used in Work package 1 guideline development.

## 3.3 Work package 3: Dose optimisation

*Optimisation* is a fundamental aspect of radiation protection. It requires that radiation doses should be kept as low as reasonably achievable. While dose limits apply to workers and the general public, there are none for patients, so limiting doses to this group is particularly important on a day-to-day basis. In practice, optimisation involves several aspects, but the focus of this Work package was to develop a quality assurance programme for dental CBCT, including the design and production of quality control phantom(s) for commercialisation. A quality control phantom is a test object containing various inserts which can be X-rayed routinely (in place of the patient). The images which are obtained can be measured as a means of checking if equipment is of a satisfactory standard and is performing consistently. It also allows clinicians to test the effect on image quality of reducing exposure factors and achieve lower doses in clinical work without “experimenting” on real patients.

### 3.3.1.Phantom design

This research involved an iterative process of design and production of prototype phantoms and testing, culminating in the production of a definitive phantom (Figure 4). This consists of a cylindrical phantom housing made of clear perspex and a number of test inserts (Figure 5) for evaluating different physical properties of the CBCT technique. Each column within the cylinder includes a separate threaded cap which allows the user to fill and empty a single column of inserts without disturbing the other columns. A 20mm deep section at the bottom of the phantom is included which is used for homogeneity measurements (testing of the uniformity of the image). A threaded hole at the bottom of the phantom means it can be securely attached to a support (e.g. a tripod or table).

The phantom and inserts were scanned on a wide range of CBCT devices and have been refined in three rounds of development, with feedback from validation informing the next round. The design changes that were implemented into the definitive phantom were found appropriate for both the body and the inserts for the different image quality tests.

***Figure 4:*** *The phantom body with seven columns for test insert accommodation, the white engraved lines (black arrow) for accurate positioning / alignment and the homogeneity 20mm deep section (white arrow) with the threaded hole at the bottom*

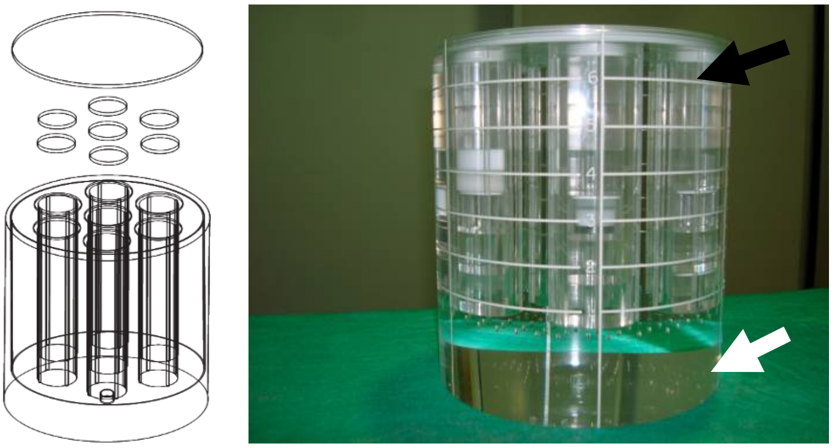


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***Figure 5:*** *The lettered threaded caps and the orientation rails*


3.3.2: Software design, implementation and validation

For the semi-automatic evaluation of phantom images, a specific software program was developed. The general idea behind the software is that the user imports the datasets of the scanned phantom into the software, performs the analysis of certain image quality parameters and enters these results into a Quality Control (QC) report. These image quality parameters are either assessed through visual analysis or user-interactive measurements.

There are two different parts to the software: (1) the graphic user interface (GUI) which allows the user to import and visualise the datasets of the scanned phantom and allows for the visual analysis of certain image quality properties, and (2) different executables (i.e. a set of instructions in a specific computer language) that allow the user to extract certain regions of interest from the dataset for automated measurement of all other image quality parameters. The two parts are merged into one package which allows for a full assessment of all phantom-related Quality Control (QC) parameters.

*First part – user interface and insert selection*

The user is able to open datasets by selecting 'File, Open set of images' in the software, then browsing to the folder containing the dataset and selecting any slice in that folder. Subsequently, reformatting in other planes is achieved using the stack of axial slices (Figure 3). The interface of the software contains four windows. On the left side, three small windows show the three plane slices. The main window can display one of these small windows in full size. After importing a dataset, by default, the axial (horizontal) slices are shown in the main window. The user can switch to the other slices by selecting one of the other small windows on the left side. By scrolling through the slices, there is a possibility for: (1) visual analysis of certain image quality parameters, (2) linear measurements to assess geometric accuracy, (3) the selection of regions of interest for automated image quality analysis. For this third step, an 'insert selection tool' is implemented, which enables the free selection of certain parts of the phantom for automated analysis.

*Second part – region extraction and automated analysis*

To start using the selection tool, the user has to click and drag to create a selection box while using the axial view, after which the borders of the selection can be adjusted in every direction and using all three slice windows (Figure 6). After the appropriate selection of a region of interest, the measurement of a certain image quality parameter is performed and the results are displayed in a pop-up window (Figure 7).

Validation of the associated software by five consortium partners was successful. A clear protocol for all measurements was established. It was found that the final software is easy to work with, that the working speed has been significantly increased, and that the measurements can be sufficiently reproducible for QC purposes. Namely, the software is able to open datasets from all available CBCT devices, it allows for the measurement of all image quality parameters that are relevant for quality control and there is a sufficient agreement between repeated measurements, either by different observers or by the same observer.

***Figure 6:*** *Software with main (right) and side (left) windows, the insert selection tool and toolbar.*

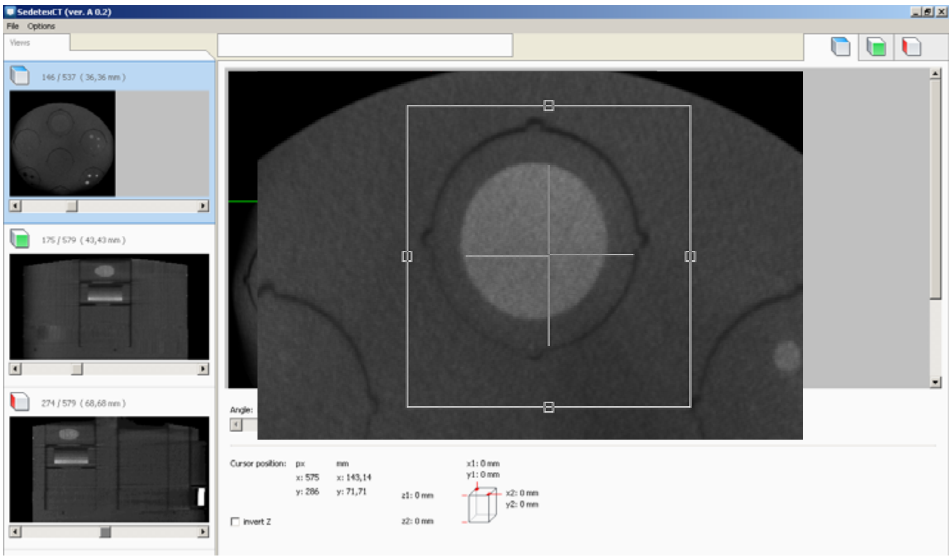
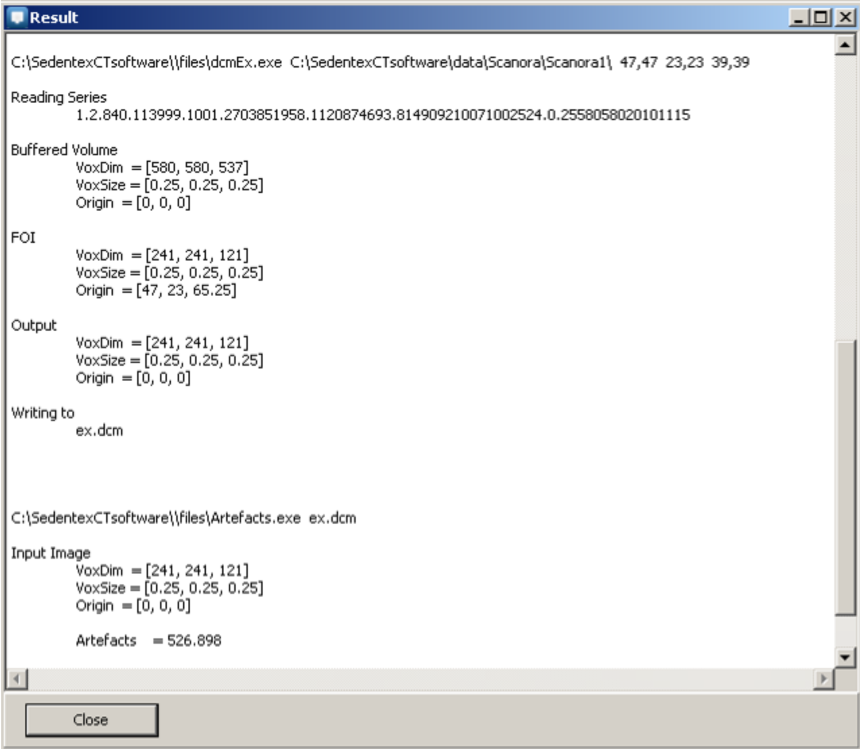


***Figure 7:*** *Pop-up window with image analysis results.*




3.3.3 Quality Assurance Programme for CBCT.

A Quality Assurance (QA) procedure protocol was formed comprising two parts. The first is a generic part about the implementation of a QA programme in CBCT that was formed based on previous knowledge on QA programmes with special consideration on the particularities of the CBCT technology. The second part, the Quality Control Manual, in general lays out the necessary testing to ensure that all parameters during the examination procedure are in accordance with the standard operating protocol, thus resulting in images with diagnostic value, without exposing the patient to unnecessary risk.

The programme of equipment tests for dental cone beam CT considers the following aspects:

- Performance of the X-ray tube and generator
- Patient dose
- Quantitative assessment of image quality
- Display screen performance

This protocol outlines those physical tests and measurements that are considered to be part of a standard quality control programme for a dental CBCT unit. It does not cover quality assurance of the clinical image (dealt with in the Guidelines developed in Work package 1).

A range of tests are appropriate for dental CBCT looking at different aspects of the equipment and image display. Some of the tests are straightforward and can be readily performed by the clinical staff using the CBCT equipment. Other tests are more complex and the input of a medical physicist is required. Therefore, the expertise required for each test is indicated in the protocol.

Routine quality control tests primarily involve comparison of results with those determined during commissioning. Significant variation, as indicated by pre-determined action levels, should be investigated, either with the help of a medical physics expert (MPE) or the equipment service engineer.

Not all possible methods of assessment are considered essential. It is important to perform enough tests to confirm that the equipment is operating as intended. More complex tests do add extra information that is helpful in the optimisation process and they are detailed here for completeness. However, whether the more detailed tests are undertaken will depend on the availability of expert support and the necessary resources.

The generic part is followed by a specific part on how to use the SEDENTEXCT tools (the phantom and the software) for running the respective image quality tests. More specifically, in the specific part of the QA procedure protocol, there is detailed instructions on the phantom handling and positioning, test inserts selection, inserts placing in the phantom and using the software for specific image quality tests, based on the knowledge acquired during the project.

The tests described in the routine QA protocol including the periodic QA tests are summarised in Table 5.

***Table 5:*** *Quality Control tests as part of the Quality Assurance programme for Dental Cone Beam Computed Tomography (CBCT) Systems.*

| | Test | Priority | Level of expertise* | Suggested frequency | Action levels** |
|---|---|---|---|---|---|
| **X-ray tube and generator** | Output repeatability | Essential | MPE | 12 monthly | Mean ±10% |
| | Output reproducibility | Essential | MPE | 12 monthly | Baseline ±10% |
| | Filtration | Essential | MPE | When new, if output changes or tube head dismantled | < 2.5mm aluminium (of which 1.5mm should be permanent) |
| | Tube potential | Essential | MPE | 12 monthly | > ±5% of intended kV |
| | Field size and alignment | Essential | MPE | 12 monthly | >10% expected field size |
| | Leakage | Essential | MPE | When new and if damage suspected | > 1000µGy hr-1 at maximum tube rating. |
| **Quantitative image Quality** | Image density values | Recommended | In house/MPE | Monthly | >10% from baseline |
| | Uniformity and artifacts | Essential | In house | Monthly | Visible artefacts on the image or >±10% of the mean |
| | Noise | Recommended | In house/MPE | 12 monthly | > ±10% from baseline |
| | Limiting resolution | Essential | In house/MPE | 12 monthly | > ±20% from baseline |
| | Contrast detail | Recommended | In house/MPE | 12 monthly | Dependent on method used. |
| | Geometrical accuracy | Essential | In house/MPE | 12 monthly | within ±2mm and ±2° |
| **Display specific** | General condition | Essential | In house | Monthly | Failure to resolve different contrasts in test pattern/ not consistent between monitors |
| | Monitor resolution | Recommended | In house | Monthly | Not consistent with baseline image |
| **Patient dose** | Patient dose index | Recommended | MPE | 12 monthly | Outside ±15% of manufacturer's specification |
| | Patient dose audit | Essential | In house/MPE | At least 3 yearly | > national or international reference level |

## 3.4 Work package 4: Diagnostic accuracy

It is obvious that a diagnostic technique, such as CBCT, should be "accurate". In other words, that it can correctly differentiate health from disease and that associated software can perform correct measurements of length, volume and angles. In addition, there are other aspects related to diagnostic accuracy, including the impact of the diagnostic method on treatment planned and on the confidence of clinicians. For CBCT, there are a vast range of clinical uses, even within a relatively small area like dentistry. In this Work package, “key” applications of CBCT were chosen to study in depth. In studies of diagnostic accuracy, there is a need for a “gold standard” against which teh performance of the diagnostic technique can be compared. This gold standard can be direct vision at surgery or histopathology, but in this work micro-CT (μCT) was sometimes used. Micro-CT is an extremely detailed radiological method used on small, laboratory, samples.

### 3.4.1 Determination of the linear, segmentation and diagnostic accuracy of CBCT, using various scanners in vitro.

Linear accuracy was assessed by measuring distances on CBCT images, obtained with different imaging parameters. Our results showed that, for the device used, the number of frames (= scan time) can be reduced without implications for linear measurements. Measuring the distance between two points does not require the smallest voxel size. Although there were no significant differences in the observers’ assessments according to kV and mA changes, it should be stated that each device needs to be tested separately, which was covered in WP3, where a quality control programme was developed.

Segmentation involves splitting the image data (usually by thresholding the picture elements by grey scale value) so that only relevant parts are retained. Segmentation accuracy was analysed both for segmenting the skull surface, useful for example in orthodontic measurements, and for segmenting the trabecular bone structure, useful in assessing bone lesions. It goes without saying that the results of this study need to be evaluated keeping in mind the radiation dose associated which each device and each setting (WP2).

Surface models generated from CBCT images deviated from 5 to 29% when compared to μCT. Intra-device comparison of deviation from the gold standard (μCT), showed a preference-setting for each device. This could be inspiring for further research on preference-settings per device per application. In trabecular bone evaluation, the parameter of overlap was found to be the most robust parameter to compare devices and assess trabecular bone structure. Overlap calculates the amount of voxels that coincide with voxels on a gold standard volume (i.e. μCT). This parameter was least influenced by the choice of the threshold value of bone. The average voxel deviation was 31%, with a range from 22 to 42%. Based on the overlap of CBCT images with μCT images, a ranking could be made between the scanners, that had great similarity with the intuitive classification of an observer.

Diagnostic accuracy was assessed by creating lesions in bone and tooth specimens, after which several observers assessed the presence of such lesions. The results of the *in vitro* tooth lesion study suggest that the CBCT technique could be a reliable diagnostic tool for detecting canine impaction and associated lateral incisor root resorption. Lesions as small as 200μm could be easily diagnosed. From a previous study it was found that additional conventional panoramic radiographs are redundant, thus additional X-ray exposure of the patient can be avoided. In addition, the radiation dose of CBCT is significantly lower compared with conventional CT, and the typical overlap of dental structures on panoramic radiography is not observed.

When assessing bone lesions, a number of defects remained undiagnosed in the CBCT images. This number differed depending on the CBCT scanners and on the size of the lesions. Identification of lesions sized 175μm was possible for the best performing CBCT. Lesions were most difficult to identify in the cortico-trabecular area (area between dense outer bone and the spongy inner bone). This is due to the inherent irregular pattern of the area. Presumably computer-aided analysis of lesions in this area would yield better results.

Another study on diagnostic accuracy of bone lesions was done on animal material: pig jaws. The results showed that the sensitivity for detecting bone lesions with various CBCT scanners ranged from 72 to 80%. Specificity ranged from 60 to 77%. It is clear that differences exist between different CBCTs in the detection of apical lesions. Although the result of this *in vitro* study based on an animal model cannot be considered a standard reference when simulating clinical situations, it highlighted the importance of combining radiological and clinical findings in the diagnosis of apical lesions.

<u>3.4.2 Determination of diagnostic accuracy for CBCT for specific clinical applications: implant placement, impacted teeth (canines and mandibular 3$^{rd}$ molars) and sinus grafting procedures.</u>

*Implant placement*

The difference in planning implants based on two dimensional and CBCT images appeared most clearly as a difference in the length of the implant and in the confidence of observers to perform surgery with the information available. It is important to use the available bone space in an optimal way, and the choices about the implants to be placed can be made with more conviction when the ‘critical boundaries’ can be assessed in all planes. Any surgical event could be better predicted with 3D than with two-dimensional images. However, more in depth research on this is required to draw firm conclusions that can be generalised. Potential complications can be foreseen by CBCT, but depend on the surgeon and followed surgical procedure as well.

It needs saying that the benefit of 3D imaging is related to volume rendering, making it possible to fully integrate data prior to surgery: anatomical, pathological, biomechanical and esthetical aspects. In implant therapy, not only the surgical approach, yet an integrated approach is indeed warranted, in contrast to e.g. wisdom tooth removal.

*Impacted teeth: third molars*

Third molars (wisdom teeth) in the lower jaw are commonly impacted and removed by dentists (Figure 8). In a minority of cases, the tooth is closely related to the large nerve which lies within the jaw. The risk of sensory damage caused by inferior alveolar nerve exposure during the surgical removal of impacted mandibular third molars can be limited with an accurate preoperative prediction of nerve exposure. Based on our results, we could not state that CBCT is better than panoramic radiography in predicting nerve exposure for average cases of impacted third mandibular molars: evidence of a close relation on two-dimensional images as well as too simple cases were excluded for ethical reasons. Difficult cases do require 3D imaging, to avoid permanent nerve injuries following third molar removal. The value of a third dimension for pre-operative planning of impacted mandibular third molars has been stressed by numerous authors. More precise information when there is a close relationship between the impacted third molar and the inferior alveolar nerve, may simplify the surgical procedure and make it considerably safer. Additionally, the patient can receive more adequate information about the procedure and the associated risk.

***Figure 8:*** *an impacted wisdom tooth on CBCT*

*Impacted teeth: canines*

CBCT was more accurate than two-dimensional conventional radiography in differentiating the position of an impacted canine and its impaction grade. The detection of ectopic canine relations and root resorption was different in CBCT and panoramic images. Mild resorption of the root did not influence the type of treatment chosen. More advanced resorptions however, may influence the therapeutic decision as in these cases it might be necessary to perform an extraction or an intervention on the root level. Based on the currently collected data, no statistically significant difference could be found between the treatment plan recommended after the evaluation of CBCT compared to assessment of conventional two-dimensional images. CBCT evaluation of impacted canines prior to surgery could reduce the number of extractions due to a better assessment of their position and their relation to the adjacent teeth, and through a greater degree of confidence about the therapy plan. To be able to draw stronger conclusions on this hypothesis, a study with a larger and more homogenous patient group would be required. The confidence of the examiners in their therapy plan based on the CBCT examination was significantly higher compared to the confidence related to two-dimensional radiographic images. None of the radiographic techniques used (two-dimensional radiography or CBCT) could accurately predict complications.

In conclusion, based on the results of this study, CBCT can recommended in the following clinical situations:

- To define the surgical access route: A vestibular or oral crown position can more accurately be defined on CBCT images.
- To guide the direction of orthodontic traction. If the radiological appearance on the 2D image shows a direct relationship with the roots of adjacent teeth. This may interfere with the path of orthodontic treatment of the impacted canine.
- To determine if root resorption is present. If there are clinical and/or radiological signs suggestive for root resorption of adjacent teeth, and if these resorption would require a specific treatment (resorption degree II or III).
- To differentiate the pain due to mechanic traction or due to a iatrogenic resorption.
- To choose optimal treatment in case of doubt: when the treating dentist cannot decide between canine extraction or orthodontic treatment of the canine.

*Sinus grafting procedures*

When placing implants in the posterior parts of the upper jaw, the air sinuses may be involved due to their close inter-relationship. In such cases, a dentist may graft bone below the soft tissue lining of the sinus to “lift” the floor, giving more room to place implants. A CBCT examination may change the treatment plan for a sinus lift procedure: sinus morphology, better visible on CBCT, is important in the prevention of postoperative complications and implant loss. CBCT allows the estimation of the necessary bone graft volume using specialized software. This in its turn increases the accuracy of harvesting a bone graft in line with the estimated useful volume. A good planning of this harvesting reduces morbidity, traumatic surgery and the duration of the surgery. In our study, CBCT increased the confidence in the treatment planning compared to panoramic imaging. Further studies are needed to follow up the postoperative complications for sinus lift planned only with conventional radiological methods compared with those that were planned using cross-sectional imaging.

## 3.5 Work package 5: Cost effectiveness

3.5.1 Analysis of the costs of CBCT examinations in terms of radiation dosage and in monetary terms

All patients involved in this study had common dental problems such as retained teeth, or had lost some of their natural teeth and were going to get implants installed in the jaw bone for area(s) where teeth had been extracted. For these groups of patients dental X-ray examinations are always performed before treatment and conventional radiological methods are used. Conventional radiological methods are (1) an overview of teeth and jaw bone – a panoramic view and (2) detailed intraoral images of teeth and jaw bone. To be able to compare the conventional methods with CBCT all patients in our study were examined with conventional methods as well as with CBCT, after ethical approval and informed consent by the patient or, for children, their parent(s).

To do a cost-analysis it is important to identify, measure and value all resources used in performing the examinations. For this purpose, we proposed a model for cost-analysis and developed different protocols that were applied during examinations with CBCT and during examinations that were performed with conventional radiological methods. The protocols deal with direct costs (such as how much the equipment costs and how much the labour costs for people involved in the examinations). Indirect costs are also identified, measured and valued and involve costs for the patient to come to the clinic, both out-of-pocket costs and the cost for time used and being away from work.

When comparing costs of conventional methods and CBCT it appeared that CBCT is more costly, which was mainly due to the higher direct costs, in particular the capital costs that comprised 43% for the new method and 17% for the conventional method of the total cost per examination. Also the cost for maintenance, accommodation and labour was higher for CBCT.

In conclusion, CBCT is more costly than conventional radiological methods used for patients with common clinical situations in dentistry. Furthermore, the model that we presented and used may assist other researchers in doing cost evaluations of methods in dentistry.

3.5.2 Comparison of the costs of CBCT between countries

We anticipated that costs of using a radiological method in dentistry differ in countries having different health care systems. We used the model describe above to calculate and compare costs for CBCT examinations in four countries – Belgium, Lithuania, Romania and Sweden. CBCT examinations were performed on patients with three different clinical conditions and costs were calculated by identifying different resources used, measurement of the amount of the resources used and a monetary valuation of the quantity of resources used.

The estimates of direct costs and indirect costs of CBCT examinations varied across the health care systems, being highest in Sweden (Malmö) and lowest in Belgium (Leuven), irrespective of the clinical condition examined. The variation in direct costs was mainly due to different capital costs for the CBCT-equipment arising from differences in purchase prices of the equipments. The average indirect costs per patient were highest in Sweden, second highest for Lithuania (Vilnius), third highest for Romania (Cluj) and lowest for Belgium. Overall, where the examination fees were charged, these comprised the major part of the indirect costs.

In conclusion, a cost evaluation of a dental radiographic method cannot be generalised from one health care system to another but must take into account the specific circumstances. The model for cost analysis provides an important input for economic evaluations in comparing costs and consequences of diagnostic methods in different health care systems, and for planning of service delivery in both public and private sectors.

3.5.3 Analysis of additional diagnostic information (diagnostic accuracy and diagnostic thinking efficacy)

In this last part of the study we investigated if radiographs from CBCT examinations change what the radiologist writes in her/his report or what the clinician decides about treatment. Protocols for assessment of radiographs were developed as well as protocols for decisions regarding diagnosis and treatment plan. Both radiologists and clinicians registered their level of confidence for every "clue" they considered.

Regarding the radiologists´ decisions there were no difference if they were assessing radiographs obtained with conventional methods as compared when having access to CBCT images. They were, however, in general more confident in their decision about the different "clues" when having access to CBCT images as compared with images from the conventional radiological methods. The time it took to assess radiographs were significantly longer for assessing CBCT images.

Clinicians changed their treatment decision in between 25% and 50% of their decisions depending on which clinical situation they were dealing with, when having access to CBCT images as compared to having access to images from the conventional methods. The change in treatment decision was, however, not always due to the information they got from the radiographic report, even if they were more confident in their decision when having access to CBCT images.

## 3.6: Work package 6: Training and valorisation

There were two aspects to this work package. The first was to produce a website for the project (including secure intranet and a depository for documents and discussion tools for the project partners) and the second, main, aspect was the development of a means of delivery of information and training on dental CBCT to stakeholders (professional groups, scientists and the public).

As a first step at the start of the project, a Work package 6 implementation group (WP6 Group) was formed from amongst the project partners. A decision had already been reached to use a web-based approach to addressing the needs of CBCT users.

3.6.1 Training needs analysis

The WP6 group began by developing a questionnaire to identify the training needs of potential website users. Transposed into an online format, it was piloted amongst Consortium members of SEDENTEXCT prior to general release. Three important stakeholder groups were consulted on the content of the website: the membership of the EADMFR, the European Federation of Organizations for Medical Physics (EFOMP) and manufacturers. An internet questionnaire to 339 EADMFR members resulted in 282 valid email addresses and 139 replies. When the internet questionnaire was sent to members of the European Federation of Organizations for Medical Physics, 28 physicists replied. Four manufacturers also replied to the questionnaire. In addition, a focus group of general dental practitioners was held to determine their needs. We used this information to develop a set of training priorities to determine the most urgent requirements for each stakeholder group. Both dentists and radiologists had similar priorities. Table 6 summarises the content requirements identified as a result of the Needs Analysis, as well as content included through other means.

***Table 6:*** *Desirable website content derived from the results of the survey with EADMFR (principally radiologists) and EFOMP (principally physicists).*

| Source | Content requirements |
|---|---|
| Project Description of Work | • Guidelines document (WP1)<br>• Work generated by other Work Packages |
| Surveys (ranked) | • Information about Radiation doses and risks of CBCT<br>• A Quality Assurance Programme for users of CBCT<br>• Information about Quality Control Test Tools for CBCT<br>• A strategy for Radiation Protection of patients<br>• A strategy for Radiation Protection of staff<br>• Evidence-based Referral/ Selection Criteria for CBCT<br>• Descriptions of the Dental clinical uses of CBCT<br>• Anatomical CBCT reference image library<br>• Dose Maps for CBCT<br>• A detailed technological description of how CBCT works<br>• A regularly updated database of links to scientific publications on CBCT<br>• An objective technical comparison of different CBCT machines<br>• Information about Radiation doses and risks of CBCT<br>• A Quality Assurance Programme for users of CBCT<br>• Information about Quality Control Test Tools for CBCT<br>• A strategy for Radiation Protection of patients |
| Development team | • Information for patients undergoing CBCT scans |

### 3.6.2 Website development

The implementation of the site was divided into two distinct phases; the prototype site and the pre-definitive site. A decision was taken to use an off-the-shelf Drupal Content Management System (CMS) application. This offered the appropriate functionality to allow Wiki development, text-based information, PowerPoint lectures, diagnostic forums/ discussion boards, appropriate accessibility standards, a secure Intranet and levels of user access. The Prototype web site was designed and built, based on the design model with iterative rapid prototyping of each major design element with partners and major stakeholder representatives. This was an exercise involving minimal content, but the technical issues were explored e.g. the look and "feel" of the website, prior to developing materials to populate it.

The pre-definitive website development was concerned with building the content through multi-author contributions to for the Wiki and through developing the training programme.

The needs analysis results were used to develop a ten module training package which would be achievable and which reflected accurately the requirements of stakeholders (Table 7). The WP6 group developed Learning Outcomes for each module using a brainstorming approach on the project intranet, detailing Knowledge and Understanding, Skills and Abilities, and Judgement and Stance.

The delivery of the training modules was considered by the WP6 group and a three-component approach was considered the most appropriate:

- Powerpoint lectures with voiceover
- "Additional materials"
- Use of the Wiki

"Additional materials" were made specific to each module. This included activities of a practical nature to allow the learner to engage in active learning. For example, the additional activities involved the learner in (1) clicking on the correct word and moving it to the correct box and (2) labelling diagrams. For some modules the "additional activity" required the reading of specific documents (e.g. Guidelines). The display of 3D DICOM models through a web interface was also developed.

***Table 7:*** *The training modules.*

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| | Title |
|---|---|
| 1 | How does CBCT work - Part 1 |
| 2 | How does CBCT work - Part 2 |
| 3 | Principles of Radiation dose and risk |
| 4 | Radiation dose and risk in CBCT |
| 5 | Justification - principles |
| 6 | Justification - referral criteria |
| 7 | Dose optimisation - patients and staff |
| 8 | Dose optimisation - quality assurance |
| 9 | Anatomy on CBCT images |
| 10 | Interpretation of pathology on CBCT images |

The project partners were each allocated responsibility for the production of assessment materials on the same basis as the training materials. It was decided that a form of multiple choice questions (MCQs) would be used in the assessment section using a series of true or false question statements where at least one statement is always true. This section was designed to allow users to save their answers in order to complete tests at a later date and to review answers after completing a test. The assessments were developed using HTML/PHP with a MySQL database recording the answers given.

All of the questions were based on the information found in the training and additional materials. Users are given a percentage mark at the end of the assessment with 70% being the condition for a pass. If this is reached a certificate can be downloaded with the user's details and those of the unit having been passed. If this mark is not reach the user can attempt to retake the assessment. In most of Europe there is no well-established system for recording or validating Continuous Professional Development (CPD). The modules and certification in the SEDENTEXCT training programme, however, do meet the requirements of the UK General Dental Council for accreditation of CPD. In the UK, dentists are required to achieve a target number of validated CPD points over a 5-year cycle for re-accreditation purposes. The SEDENTEXCT training programme would contribute to such requirements.

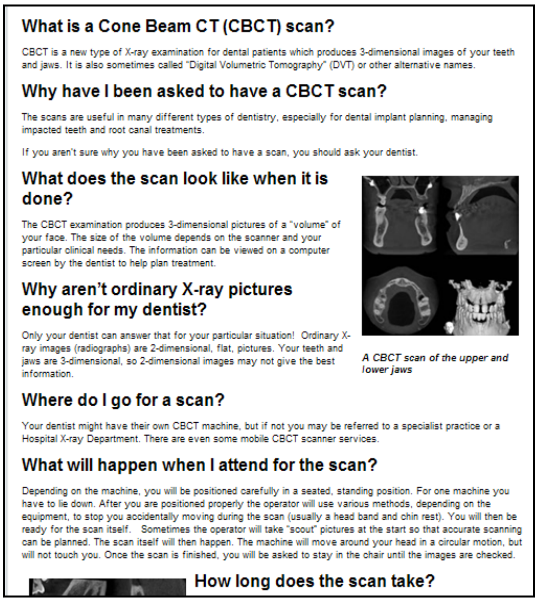
### 3.6.3: Definitive website

Visitors to the website at www.sedentexct.eu are met by a home page with links to other pages (Figure 9). The general design has been consistent, although "banners" highlighting new material have been added and removed as appropriate during the project lifetime. One of the key home page links is to the Guidelines developed through WP1 (see Section 3.1). Also highlighted is a link to

“Information for patients”, a one page series of questions and answers designed to support patient understanding of dental CBCT (Figure 10).

***Figure 9:*** *SEDENTEXCT home page.*


***Figure 10:*** *Part of the “Information for patients” web page.*



**What is a Cone Beam CT (CBCT) scan?**

CBCT is a new type of X-ray examination for dental patients which produces 3-dimensional images of your teeth and jaws. It is also sometimes called "Digital Volumetric Tomography" (DVT) or other alternative names.

**Why have I been asked to have a CBCT scan?**

The scans are useful in many different types of dentistry, especially for dental implant planning, managing impacted teeth and root canal treatments.

If you aren't sure why you have been asked to have a scan, you should ask your dentist.

**What does the scan look like when it is done?**

The CBCT examination produces 3-dimensional pictures of a "volume" of your face. The size of the volume depends on the scanner and your particular clinical needs. The information can be viewed on a computer screen by the dentist to help plan treatment.

*A CBCT scan of the upper and lower jaws*

**Why aren't ordinary X-ray pictures enough for my dentist?**

Only your dentist can answer that for your particular situation! Ordinary X-ray images (radiographs) are 2-dimensional, flat, pictures. Your teeth and jaws are 3-dimensional, so 2-dimensional images may not give the best information.

**Where do I go for a scan?**

Your dentist might have their own CBCT machine, but if not you may be referred to a specialist practice or a Hospital X-ray Department. There are even some mobile CBCT scanner services.

**What will happen when I attend for the scan?**

Depending on the machine, you will be positioned carefully in a seated, standing position. For one machine you have to lie down. After you are positioned properly the operator will use various methods, depending on the equipment, to stop you accidentally moving during the scan (usually a head band and chin rest). You will then be ready for the scan itself. Sometimes the operator will take "scout" pictures at the start so that accurate scanning can be planned. The scan itself will then happen. The machine will move around your head in a circular motion, but will not touch you. Once the scan is finished, you will be asked to stay in the chair until the images are checked.

**How long does the scan take?**

At the bottom of the home page are six picture links:

- CBCT Info
- Forums
- Guidelines
- The project
- CBCT Publications
- CBCT Training

*“CBCT Info”* is the link into the wiki. This element consists of many interlinked information pages, constructed by registered users, with internal and external links. The *“Forums”* permit users to post items of interest and permit discussion (Figure 11). *“Guidelines”* is an additional link to the SEDENTEXCT Guideline document, but also includes national guidelines identified during the project. *“The project”* link leads to descriptions of the SEDENTEXCT project and its Work packages.

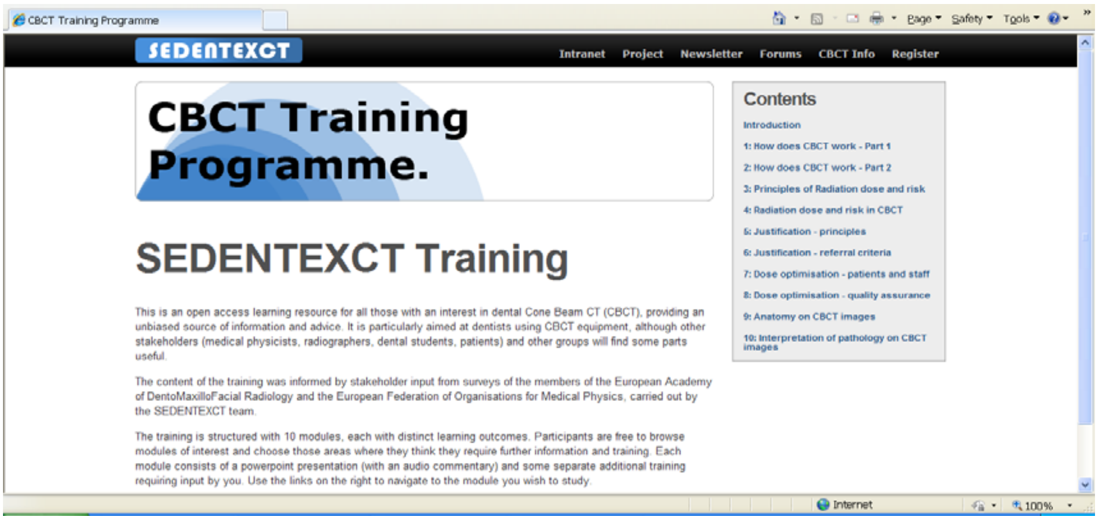
*"CBCT publications"* provides abstracts of scientific publications on dental CBCT obtained from the WP1 literature searches. The final picture link is to the CBCT Training programme (see below).

***Figure 11:*** *a page from the Discussion forum.*


*CBCT Training Programme*

The training programme is accessed from either the picture link or a banner on the home page (Figure 12). These link to a main training contents page (Figure 13) and from here the individual Modules and elements (training materials, exercises and assessments) can be accessed.

***Figure 12:*** *Opening page for the CBCT training programme.*




A common element in each module is a Powerpoint presentation with voiceover. This opens in a separate window (Figure 14) and can be viewed as often as the user wishes.

***Figure 13:*** *A module page from the training programme.*

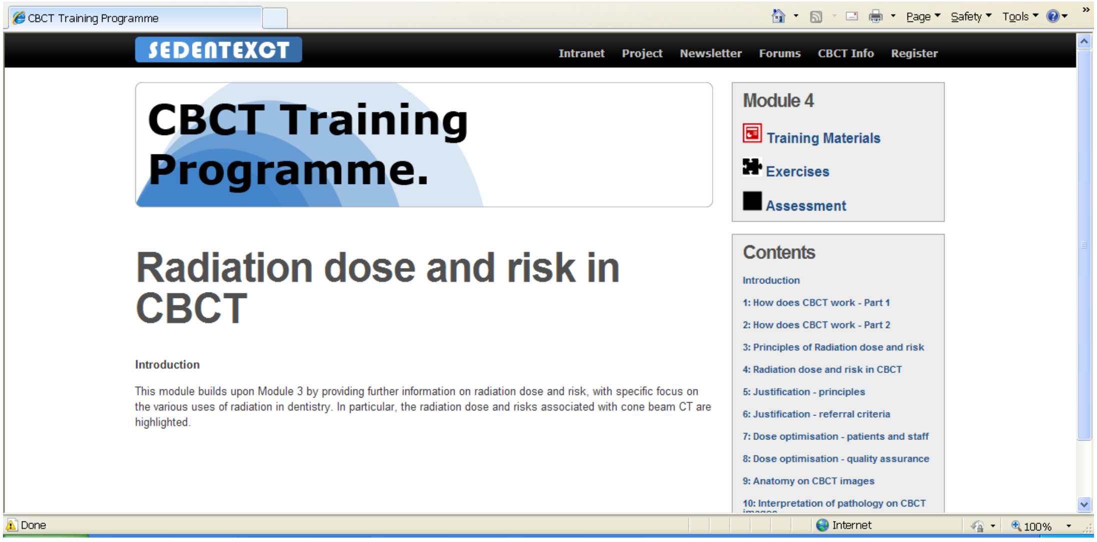



***Figure 14:*** *A Powerpoint presentation for one of the modules.*


*Future work and development.*

At the conclusion of the SEDENTEXCT project, a functional web-based source of information and training for stakeholders on dental CBCT has been produced. The website content has been copied onto the EADMFR website (www.eadmfr.info). EADMFR is the natural custodian of the training and educational material beyond the project lifetime. The material will inevitably require updating and further development, reflecting the continued evolution of dental CBCT and accumulating scientific knowledge. The website and training programme developed, however, forms a valuable foundation for the future.

# 4. Potential Impact

## 4.1 Impact and main exploitation results

This section describes the expected impact of the project, including the socio-economic impact and wider societal applications. It also describes the main exploitation results to date and the outputs of the project that are expected to be sustainable after the project, by commercial or non-commercial exploitation.

The key stakeholder groups addressed through the SEDENTEXCT project are:

- Policy makers, e.g. national and international radiation protection agencies and professional bodies in dentistry and medical physics
- Researchers in dentistry, medical physics and health economics
- Practising dentists and medical physicists
- Manufacturers of cone beam CT equipment
- The general public

SEDENTEXCT is expected to have a major influence on the **development of national and international guidelines for use of CBCT** produced by radiation protection agencies and as European Guidelines. As CBCT examinations are associated with higher radiation dose than most conventional radiological methods in dentistry, it is of utmost importance to draw attention to important radiation safety aspects related to the use of CBCT technology. One important way of reducing radiation dose to patients is to use proper selection criteria to use CBCT only when it benefits the patient. The increased knowledge on advantages and disadvantages of the use of CBCT that is a result of our work will increase patient safety as there will be more relevant referrals on CBCT examinations and use of CBCT. The work may also inform social security regulations on allowable treatments for reimbursement.

The results of this study will ensure that clinicians have a clearer understanding of when to use CBCT as well as the importance of dose limitation when undertaking cone beam computed radiography. Consideration has also been given to the ethical use of CBCT as well as developing strategies to reduce inappropriate practice and also inconsistency in clinical care. In addition, the study found that research was urgently needed in the field of diagnostic accuracy.

The **Basic Principles** were published in 2009 (Horner et al.) and provide a framework of standards achieved by consensus for the clinical use of cone beam CT. The Basic Principles have already influenced the Norwegian, Belgian, French and UK Guideline documents. The evidence-based **SEDENTEXCT Guidelines** are available at http://www.sedentexct.eu/content/guidelines-cbct-dental-and-maxillofacial-radiology. Both the Basic Principles and Guidelines are expected to be reproduced in other documents, papers etc. by scientists, clinicians and regulatory authorities, including national and international guideline and standards documents. The SEDENTEXCT Guidelines also direct research into diagnostic accuracy studies where evidence is missing or lacking. The SEDENTEXCT project has remained in contact with the Article 31 Expert group (later WP-MED) throughout the project, with a view to acceptance of the SEDENTEXCT Guidelines as European guidelines on CBCT, and WP-MED will consider this formally at their meeting in October 2011.

The SEDENTEXCT **results on the clinical applications of CBCT** are the subject of several papers in preparation and provide information about the diagnostic efficacy of CBCT in dentomaxillofacial applications, thus contributing to the development of national and international guidelines.

The **Quality Assurance (QA) Manual** forms part of the SEDENTEXCT Guidelines and is also available independently. The QA Manual provides the basic quality assurance principles and methods for optimised performance of dental CBCT systems and optimised radiation doses for patient and staff. Dentists and radiologists will benefit from following the QA protocol, ensuring that their CBCT equipment operates efficiently in terms of output image quality. In developing the QA Manual, the project's conclusions on personnel protection from measurements of the scatter dose were considered. It is expected that the QA Manual will be reproduced in other documents, such as information sheets accompanying newly purchased CBCT devices and phantoms. The QA Manual already accompanies the SEDENTEXCT phantom. The quality control programme is additionally included in the information pages of the SEDENTEXCT and EADMFR websites.

The **SEDENTEXCT quality control (QC) phantom** has a patent pending and commercial sales have begun through LTO and appointed regional distributors. The phantom is a tool for measuring image quality and dose for dental CBCT systems. Apart from the routine use of the QA protocol and phantom for long-term assessment of CBCT performance, the phantom can also be used as a tool for CBCT optimisation. The phantom is applicable on all CBCT devices that are currently on the market. Furthermore, it can be applied to any new or upgraded devices that will be released in the coming years, providing an initial assessment of imaging performance. By using the QC phantom and evaluating technical image quality parameters in relation with radiation dose, it can be ensured that new and upgraded CBCT devices are optimized for dental imaging. Potentially every CBCT system in clinical or research use throughout the EU and beyond could use the phantoms as a common standard for measurement of image quality and dose. Furthermore, a customized dosimetry phantom was produced and is being marketed, enabling the measurement of two dose indices which can be used for device intercomparison, dose optimization or quality control.

The **SEDENTEXCT phantom software** facilitates interpretation of the results obtained from scanning the QC phantom, aiding the speed of use of the SEDENTEXCT phantoms. LTO plan either to sell the software or bundle it with the SEDENTEXCT phantoms, and will continue to develop and refine the software. An Intellectual Property Rights (IPR) agreement will shortly be finalised allowing both co-developers of the software (LTO and the Katholieke Universiteit Leuven) to continue to develop the software.

The availability of the quality control (QC) phantom, software and QA Manual is expected to have a great impact on several stakeholder groups. Medical physicists may use the same phantom and software for advanced imaging performance tests on CBCT units. The research community may use the phantom and the software for further studies on imaging characteristics. The QC phantom can be used as a research tool for various applications. Algorithmic improvement of CBCT image quality can be investigated using raw data of the phantom. Improvements of image reconstruction in terms of advanced image properties, (e.g. noise, spatial and contrast resolution, metal artefacts) can be evaluated this way. Finally, the CBCT unit manufacturers may use the phantom and the software for testing prototypes units, their new equipment before delivery and any new features added to their units.

Researchers and manufacturers can use the **image analysis results** obtained from the range of CBCT devices and protocols used in the SEDENTEXCT project to continue research and development on image quality optimisation. Using the SEDENTEXCT phantom, new measurements can be obtained from any new device or protocol, and results can be directly compared to previously obtained measurements. Thus, SEDENTEXCT provides standardised measurement of image quality on CBCT, definition of different optimisation strategies, and quantification of the improvement of image quality through exposure adjustment or reconstruction.

The **dose index definitions and conversion factors** are the subject of papers in preparation and provide a relatively quick and easy way of estimating the effective radiation dose received by typical adult and paediatric patients for different CBCT devices and exposure protocols, compared with using direct measurements. The risk to a typical patient could be estimated and optimisation techniques could be developed. A thorough investigation of the dose distribution has led to the definition and validation of different specific dose indices. Additional information was obtained through *in vivo* skin measurements and Monte Carlo simulations, and conversion factors were defined to relate a technical dose index to the effective dose. It is expected that the dose indices defined in WP2 will be incorporated into practice and lead to a standardisation of the measurement of CBCT exposures. Furthermore, the results will lead to an optimisation of patient and personnel doses by adhering to the principles defined in the SEDENTEXCT Guidelines.

A clear understanding of the dose ranges obtained with CBCT imaging, the factors that influence this dose, and the possibilities for reducing it in practice can lead to a more optimised use of CBCT in terms of dose reduction. The project has provided a large amount of dosimetric data, greatly increasing the knowledge of radiation dose in CBCT as well as addressing a few major gaps in the literature. The effect of different exposure parameters on patient dose was assessed, and can be related to image quality parameters. The **dose measurement results** increase the general knowledge on the dose range in CBCT imaging, and enable clear and evidence-based definitions of dose optimisation strategies. The results are expected to have a significant direct or indirect impact on the research community, clinical users of CBCT and CBCT manufacturers. The research has been incorporated into the SEDENTEXCT Guidelines, providing different dose limitation strategies. Also, the dosimetric work fed into the QA Manual, as part of the work encompassed radiation dose.

SEDENTEXCT provides a valuable contribution to **diagnostic accuracy studies** in the research community. There has been much discussion at national and international scientific meetings on the research subject of diagnostic accuracy of CBCT. SEDENTEXCT has provided some important findings that might be important for similar research. At the very beginning of the process, we came across a boundary: to perform diagnostic accuracy studies, in the strict definition thereof, is not obvious with the type of data and applications with which we worked. Indeed, diagnostic accuracy requires a gold standard. In an *in vivo* context, it is not always feasible to work with this principle. That is why, early in the process, we decided to focus on the comparison between 2D and 3D images as well as the surgical outcome. We feel it might be worth developing a scientifically sound approach for studies on the justification of the use of new radiological technology, a guide with research standards for scientists to follow when performing research in this area. As such, it would become also easier to compare previous research. This is quite laborious to date, due to the rather unsystematic approach of different authors.

Another general comment concerns the follow-up of patients. Within the framework of the current project, a long-term follow-up was not feasible. However, it is exactly this long-term follow-up that might strongly differentiate the 2D from the 3D approach. This goes most of all for the canine study, where the approach might show its implications only after the entire therapy process has been completed.

The diagnostic accuracy work on **surface segmentation** and will assist in CBCT-based surgical planning. Its main applicability will be the planning of implant placement. On the basis of the outcome of present surface segmentation studies, companies specialising in CBCT-based surgical planning software and/or CBCT manufacturers may integrate guidelines and protocols for their customers on how to optimise exposure parameters for a specific CBCT scan of either an upper or lower jaw. The present surface segmentation study might be elaborated to provide data based on larger datasets.

The work on diagnostic accuracy of **trabecular bone segmentation** will help provide objective measures of bone quality. Its main applicability will be the planning of implant placement, assessment of periodontal tissues and follow-up of bone lesions such as osteonecrosis, bone tumours, etc. Companies specialising in CBCT-based surgical planning software and/or CBCT manufacturers may integrate guidelines and protocols for their customers on how to interpret bone quality from a specific CBCT scanning. Dentists could apply this technique on CBCT to obtain more insight in the local bone structure and thus predict if a potential host bed is of good quality, is healing well and could potentially allow a successful implant placement. The present method for trabecular segmentation might be elaborated to provide data based on larger datasets.

In May 2011, a consensus meeting on the guidelines on preoperative imaging for implant placement took place in Warsaw. This meeting was attended by SEDENTEXCT delegates, the European Association for Osseointegration (EAO), the European Academy of Dentomaxillofacial Radiology (EADMFR) and the Computer Aided Implantology Academy (CAIA).

The **health economics methodology** is the subject of papers in preparation and can be used to compare the economic costs of CBCT in different dental health care contexts and the factors contributing to those costs, leading to an improved return on investment in health care resources and increased efficiency in health care resource utilisation. In recent decades there has been increasing recognition of the need to consider cost in diagnostic methods in medicine and dentistry. Cost-effectiveness analysis is an objective systematic technique of comparing alternative health care strategies on both costs and effects simultaneously. The research on costs and effects in SEDENTEXCT is among the first studies within the field of diagnostic imaging in dentistry and will have impact on practice guidelines on the use of CBCT. Furthermore, there will be an impact on the design of future studies on diagnostic methods and support for researchers within the field.

Finally, the **SEDENTEXCT website** www.sedentexct.eu, including the **training materials,** provides a valuable information resource and training for a wide range of people interested in CBCT. The SEDENTEXCT website is designed to bring information about CBCT in dentistry to dentists, medical physicists, radiologists and other concerned healthcare professionals, CBCT equipment manufacturers, undergraduate and postgraduate students, as well as the general public. A prominent feature of the website home page is a link to 'information for patients' which consists of a 'Frequently Asked Questions' answering a wide range of queries patients may have before undergoing a scan themselves. The hope is that this will allay any fears members of the public may have regarding such a procedure, by laying out the details of the procedure for them, prior to their appointment.

At a general level the site provides detailed information on CBCT in dentistry to any interested party, including the general public. The CBCT Information section of the site provides general information on the subject for the layperson. The SEDENTEXCT newsletter also includes readily accessible information on the subject, and the project itself. For professionals with an interest in CBCT in dentistry, the website provides a deeper layer of information, beyond the general information which is likely to be accessed by members of the public. By following links from these general pages it is possible for dentists to learn more about the physics behind the operation of CBCT machines, the reasons for artefacts in images and how to minimise them and a wealth of other information which is unlikely to have been covered during their formal training in dentistry. Likewise physicists can study the ways in which CBCT is useful in dentistry and the issues which are faced by dentists, such as minimising field of view and patient protection. The website also acts as a vehicle for the delivery of the SEDENTEXCT Guidelines document. This document is freely available as a download from the site.

Of even greater interest to the healthcare professionals will be the training section of the website. This training programme is divided into ten modules which cover a wide range of topics relevant to users of CBCT devices in a modern dental setting. Introductory modules set the scene and ensure that a basic level of understating is reached before the later modules tackle issues such as patient protection, diagnostic efficacy, and interpretation of normal dental anatomy and dental pathology.

The resources will have an impact on education at different levels, undergraduate as well as post-graduate and in continuing professional development courses, which consequently will benefit patients. The training materials are already suitable for accreditation of Continuous Professional Development (CPD) for dentists in the UK. However, there is so much variation in how CPD is accredited across different European countries that further work would be needed after the project to make the training materials more widely accredited. By transferring the website's information resources to the European Academy of DentoMaxilloFacial Radiology, the project team has ensured that these resources can be maintained and further developed after the end of the project.

## 4.2 Main dissemination activities

The SEDENTEXCT dissemination activities were guided by the Communication Action Plan, which was reviewed as the project developed. This stated that 'SEDENTEXCT aims to communicate with those inside and outside the research, medical physics and dental communities'. Our principal types of dissemination activity were:

| | |
|---|---|
| SEDENTEXCT newsletter | Members of professional associations, radiation protection agencies, manufacturers, researchers |
| SEDENTEXCT Workshop | Members of professional associations, radiation protection agencies, manufacturers, researchers |
| Journal papers | Researchers, members of professional associations, manufacturers |
| Presentations at conferences | Researchers, members of professional associations, manufacturers |
| Influencing national and international guidelines for use of CBCT | Policy makers |
| Commercial dissemination activities with regard to sales of the SEDENTEXCT phantoms | Practising radiologists, medical physicists and researchers |
| SEDENTEXCT website | All stakeholders |

At an early stage in the project, a mailing list was developed, comprising principally of contacts at professional associations, radiation protection agencies, CBCT manufacturers, universities, researchers, and individuals who requested to be included on the mailing list. This list included dissemination to the European Academy of DentoMaxilloFacial Radiology (EADMFR), the European Federation of Organisations for Medical Physics, and the ORADLIST mail base. The estimated audience for the newsletter is up to 75,000 people, subject to the professional organisations contacted circulating the newsletter to their members.

*SEDENTEXCT newsletter*

The project produced twice-yearly newsletters, which were disseminated via the mailing list and remain available on the SEDENTEXCT website. The newsletters included an editorial from Professor Keith Horner, information about progress in the project, significant results, papers and presentations, and biographies of SEDENTEXCT young researchers and other project personnel.

*SEDENTEXCT workshop*

An end-of-project workshop entitled "The State of the Art" SEDENTEXCT Workshop on dental Cone Beam CT' took place on 31 March 2011 in Leeds, UK. This was a public workshop organised by, and taking place as part of, a conference of the British Society of Dental and Maxillofacial Radiology. The workshop described the main outputs of the project to an enthusiastic audience of over 100 people from the main stakeholder groups. CBCT manufacturers were well represented, as they were interested in the comparisons of CBCT machines undertaken within the project. Several manufacturers ran marketing stands in association with the workshop, and SEDENTEXCT's commercial partner Leeds Test Objects took the opportunity to market the SEDENTEXCT phantoms.

*Journal papers*

There is always a long delay between submission of papers to journals and their eventual publication. Three papers were published during the lifetime of the project, including the 'Basic Principles' paper which provided the framework agreed by consensus on which the SEDENTEXCT Guidelines would be based. A further three papers have been accepted for publication, and 24 papers are in development or have been submitted, covering all the major research outputs of the project. The papers have been published in, or are targeted at, major journals in dentomaxillofacial radiology and medical physics.

*Conference presentations*

The major peer-reviewed conferences specialising in dentomaxillofacial radiology are the European Congress of Dentomaxillofacial Radiology (ECDMFR) and its worldwide equivalent, the International Congress of Dentomaxillofacial Radiology (ICDMFR), each on a two yearly cycle such that one or other takes place each year. These conferences provided major annual dissemination opportunities for the project.

ECDMFR (Budapest, 2008) provided an opportunity for a workshop discussion with experts, chaired by one of the SEDENTEXCT partners, which formed part of the groundwork for development of the Basic Principles. SEDENTEXCT members gave peer-reviewed conference presentations of work undertaken within the project, giving nine presentations at ICDMFR (Amsterdam, 2009) and seven presentations at EADMFR (Istanbul, 2010). One of the Amsterdam papers (Pauwels et al, 2009) was a finalist in the IADMFR Research award. ICDMFR 2011 took place in Hiroshima, Japan, which limited attendance to presentation of four papers (two funded by SEDENTEXCT with the agreement of the EC Project Officer), though by this stage of the project, partners were focusing on journal papers. One of the SEDENTEXCT-funded papers at Hiroshima was accepted as a keynote presentation (Rohlin et al, 2011) and a non-funded paper achieved second prize in the IADMFR research award (Vandenberghe et al, 2011).

Partners presented SEDENTEXCT work at a number of other peer-reviewed conferences, including the World Conference on Medical Physics and Biomedical Engineering (WCMPBE), conferences of the Institute of Physics and Engineering in Medicine (IPEM) and the European Society of Head and Neck Radiology (ESHNR).

In addition to the presentations specifically disseminating aspects of SEDENTEXCT research, partners undertook general dissemination of the project, as a slide or two within presentations at other conferences and events. While not funded by SEDENTEXCT, these general dissemination activities have been important in raising wider awareness of the project. General dissemination has taken place at research conferences, within training courses for professionals and university students, and to professional associations.

*Influencing national and international guidelines for use of CBCT*

Throughout the project, SEDENTEXCT members have sought opportunities to influence national and international guidelines for use of CBCT. Early in the project, the Basic Principles document was passed to the Euratom Article 31 Expert group, a group of experts in radiation and public health who are attached to the European Commission in an advisory role (http://ec.europa.eu/energy/nuclear/radiation_protection/article_31_en.htm). The Chair of the group responded by distributing the document to members and offering to aid in distribution to member states. Later in the project, the WP-MED group advising the European Commission on radiation protection issues was asked to comment on the draft of the SEDENTEXCT Guidelines version 2.0, with a view to possible publication of the Guidelines in its official "Radiation Protection" publication series. The WP-MED group will discuss publication of the Guidelines at their meeting in October 2011.

Individual SEDENTEXCT members have also been directly involved in influencing policy through, for example, membership of the UK Health Protection Agency's Working Group on Dental Cone Beam CT, which led to the development of UK national guidelines, and through informal contacts with people developing guidelines in other European countries.

Finally, the SEDENTEXCT Guidelines (versions 1.0 and 2.0) have been disseminated to policy makers and others via the SEDENTEXCT mailing list.

*Commercial dissemination activities*

The SEDENTEXCT partner Leeds Test Objects (LTO) produced a marketing plan for the SEDENTEXCT phantoms and is marketing them through commercial distributors. While much of the marketing is undertaken by the distributors, LTO has raised awareness of the phantoms in a number of ways. The phantoms are marketed on LTO's website, and LTO exhibited the phantoms at the European Congress of Radiology (Vienna, 2011). LTO have also produced an information sheet (flyer) describing the phantoms, and have used a mailshot to raise awareness with CBCT device manufacturers. In addition, the marketing of the phantom has benefited from awareness-raising through inclusion in the SEDENTEXCT newsletter, which has a very wide distribution.

*SEDENTEXCT and EADMFR website*

The SEDENTEXCT website www.sedentexct.eu has provided information about the project and CBCT from an early stage in the project, including an information sheet for patients. The website appears on the first page of the Google search for 'cone beam CT' (22 July 2011). During the project, the website was enhanced to include training materials on CBCT, aimed at novices in CBCT. The training materials have been carefully written to be accessible to anyone with a general scientific background, so are suitable for continuing professional development, university education and members of the general public interested in CBCT.

At the end of the project, the SEDENTEXCT website information resources were transferred to the website of the European Academy of DentoMaxilloFacial Radiology (EADMFR). The SEDENTEXCT resources are available directly from the EADMFR home page www.eadmfr.info.

*Other dissemination activities*

During the course of the project, SEDENTEXCT has collaborated with a number of other projects running in partner institutions in Leuven, Belgium and Cluj-Napoca, Romania. It has also collaborated with projects in national organisations, such as the Greek Atomic Energy Commission.

In February 2009, SEDENTEXCT issued a joint press release with EADMFR concerning the Basic Principles, and a further press release concerning the Definitive Guidelines will be issued in September 2011.

Finally, SEDENTEXCT was mentioned in an article in the New York Times ("Radiation worries for children in dentists' chairs"; 22 November 2010), within an article on safety of CBCT for paediatric use.

# 5. Contact Details


Website: www.sedentexct.eu

Contact: Professor Keith Horner
University of Manchester
School of Dentistry
Coupland Three
Higher Cambridge Street
Manchester M13 9PL
UK

Tel: +44 (0) 161 275 6640
E-mail: keith.horner@manchester.ac.uk


### Partners

The University of Manchester (UK) (Project Coordinator)
The National and Kapodistrian University of Athens (Greece)
"Iuliu Hatieganu" University of Medicine and Pharmacy in Cluj-Napoca (Romania)
Leeds Test Objects Ltd. (UK)
Katholieke Universiteit Leuven (Belgium)
Malmö University (Sweden)
Vilnius University (Lithuania)

### References


Horner K, Islam M, Flygare L, Tsiklakis K, Whaites E (2009) “Basic Principles for Use of Dental Cone Beam CT: Consensus Guidelines of the European Academy of Dental and Maxillofacial Radiology”, Dentomaxillofacial Radiology 38, 187-195.

Pauwels R, Stamatakis CH, Manousaridis G, Walker A, Michielsen K, Bosmans H, Jacobs R, Horner K, Tsiklakis K, The SEDENTEXCT Project Consortium (2009), “Image analysis of a quality assurance phantom for cone beam CT” presented at the 17th International Congress of Dentomaxillofacial Radiology 28 June - 02 July, 2009 Amsterdam, The Netherlands.

Rohlin M, Christell H, Birch B, Horner K, Lindh C, the SEDENTEXCT Project Consortium (2011) "Cost evaluation of CBCT imaging in oral health care with examples of SEDENTEXCT" presented at the 18th International Congress of Dentomaxillofacial Radiology 25-29 May 2011, Hiroshima, Japan.

Vandenberghe B, Luchsinger S, Hostens J, D'hoore E, Jacobs R, the SEDENTEXCT Project Consortium (2011) "The influence of exposure parameters on jaw bone model accuracy" presented at the 18th International Congress of Dentomaxillofacial Radiology 25-29 May 2011, Hiroshima, Japan.

**TEMPLATE A1: LIST OF SCIENTIFIC (PEER REVIEWED) PUBLICATIONS, STARTING WITH THE MOST IMPORTANT ONES**

| NO. | Title | Main author | Title of the periodical or the series | Number, date or frequency | Publisher | Place of publication | Year of publication | Relevant pages | Permanent identifiers[1] (if available) | Is/Will open access[2] provided to this publication? |
|---|---|---|---|---|---|---|---|---|---|---|
| 1. | Basic Principles for Use of Dental Cone Beam CT: Consensus Guidelines of the European Academy of Dental and Maxillofacial Radiology | K. Horner | Dentomaxillofacial Radiology | 38 | The British Institute of Radiology | UK | 16/02/2009 | 187-195 | doi: 10.1259/dmfr/74941012 | No |
| 2. | Effective dose range for dental cone beam computed tomography scanners. | R. Pauwels | European Journal of Radiology | Monthly | Elsevier | USA | 31/12/2010 ePub ahead of print | 5 | doi:10.1016/j.ejrad.2010.11.028 | No |
| 3. | Paediatric organ and effective doses in Dental Cone Beam Computed Tomography | C. Theodorakou | WC2009, IFMBE Proceedings | 25/3 | SpringerLink | | 7/09/2009 | 305-308 | doi: 10.1007/978-3-642-03902-7_86 | No |

[1] A permanent identifier should be a persistent link to the published version full text if open access or abstract if article is pay per view) or to the final manuscript accepted for publication (link to article in repository).
[2] Open Access is defined as free of charge access for anyone via Internet. Please answer "yes" if the open access to the publication is already established and also if the embargo period for open access is not yet over but you intend to establish open access afterwards.

## TEMPLATE A2: LIST OF DISSEMINATION ACTIVITIES

| NO. | Type of activities[1] | Main leader | Title | Date | Place | Type of audience[2] | Size of audience | Countries addressed |
|---|---|---|---|---|---|---|---|---|
| 1 | Workshop | UNIMAN | "The State of the Art" SEDENTEXCT Workshop on Dental Cone Beam CT | 31 March 2011 | Leeds, UK | Scientific community, civil society, industry, policy makers | 112 | UK, Europe |
| 2 | Workshop | UNIMAN | "Dental radiology – the forgotten problem" (K. Horner, Joint EC and International Atomic Energy Authority Workshop on Justification of Diagnostic Imaging Exposures) | 2-4 September 2009 | Brussels, Belgium | Policy makers | 100 | International |
| 3 | Workshop | NKUA, UNIMAN | "Cone Beam CT Debate / Discussion" (ECDMFR) | 28 June 2008 | Budapest, Hungary | Scientific community, industry, civil society, policy makers | 250 | Europe |
| 4 | Workshop | UNIMAN | Interactive session on CBCT justification (K. Horner, ICDMFR) | 28 June – 2 July 2009 | Amsterdam, Netherlands | Scientific community, civil society, industry, policy makers | 350 | International |
| 5 | Conference | UNIMAN | "Risk from dental CBCT and risk reduction-SEDENTEXCT"(C. Theodorakou, 2nd NOTE Annual Meeting) | 15-18 September 2008 | Galway, Eire | Scientific community | 100 | Europe |
| 6 | Conference | VU | "SEDENTEXCT: a 7th Framework Programme Euratom Project to Increase Safety and Efficacy of Cone Beam Computed Tomography'"(D. Ivanauskaite, 3rd Baltic Scientific Conference in Dentistry) | 6-8 November 2008 | Vilnius, Lithuania | Scientific community, industry | 350 | Lithuania, Latvia, Estonia, other European countries |
| 7 | Conference | UNIMAN | "Risk from dental cone beam computed tomography and risk reduction-SEDENTEXCT project" (C. Theodorakou, UK RC 09) | 8-10 June 2009 | Manchester, UK | Scientific community, civil society, industry | 2,000 | UK |

[1] A drop down list allows choosing the dissemination activity: publications, conferences, workshops, web, press releases, flyers, articles published in the popular press, videos, media briefings, presentations, exhibitions, thesis, interviews, films, TV clips, posters, Other.
[2] A drop down list allows choosing the type of public: Scientific Community (higher education, Research), Industry, Civil Society, Policy makers, Medias ('multiple choices' is possible.

| NO. | Type of activities[1] | Main leader | Title | Date | Place | Type of audience[2] | Size of audience | Countries addressed |
|---|---|---|---|---|---|---|---|---|
| 8 | Conference | CLUJ | “The accuracy of CBCT in the assessment of artificially induced periapical bone lesions for deciduous and permanent teeth” - O 09, p 29 (M Baciut, ICDMFR) | 28 June – 2 July 2009 | Amsterdam, Netherlands | Scientific community, civil society, industry, policy makers | 350 | International |
| 9 | Conference | MAHOD | “Economic evaluation in oral health” (H. Christell, ICDMFR) | 28 June – 2 July 2009 | Amsterdam, Netherlands | Scientific community, civil society, industry, policy makers | 350 | International |
| 10 | Conference | UNIMAN | “Entrance skin dose measurements in dental CBCT” (L. Cockmartin, ICDMFR) | 28 June – 2 July 2009 | Amsterdam, Netherlands | Scientific community, civil society, industry, policy makers | 350 | International |
| 11 | Conference | CLUJ | “CBCT accuracy for detection and measurement of bone defects – a comparative study with stereomicroscopy as a gold standard” O-76, p 73. (M. Hedesiu, ICDMFR) | 28 June – 2 July 2009 | Amsterdam, Netherlands | Scientific community, civil society, industry, policy makers | 350 | International |
| 12 | Conference | KUL | “Radiographic detection of artificial bone lesions in an *in vitro* mandible” (S. Martens, ICDMFR) | 28 June – 2 July 2009 | Amsterdam, Netherlands | Scientific community, civil society, industry, policy makers | 350 | International |
| 13 | Conference | MAHOD | Measuring absorbed dose in a humanoid phantom irradiated with a dental cone beam CT comparison to conventional dental CT (M Nilsson, ICDMFR) | 28 June – 2 July 2009 | Amsterdam, Netherlands | Scientific community, civil society, industry, policy makers | 100 | International |
| 14 | Conference | KUL | “Image analysis of a quality assurance phantom for cone beam CT” (R. Pauwels, ICDMFR) | 28 June – 2 July 2009 | Amsterdam, Netherlands | Scientific community, civil society, industry, policy makers | 350 | International |
| 15 | Conference | NKUA | “The use of a specifically developed CBCT quality control phantom for examining the correlation between CBCT pixel intensity values and medical CT numbers” (H. Stamatakis, ICDMFR) | 28 June – 2 July 2009 | Amsterdam, Netherlands | Scientific community, civil society, industry, policy makers | 350 | International |
| 16 | Conference | UNIMAN | “A survey of organ and effective doses for seven dental cone beam computed tomography (CBCT) units” (C. Theodorakou, ICDMFR) | 28 June – 2 July 2009 | Amsterdam, Netherlands | Scientific community, civil society, industry, policy makers | 350 | International |
| 17 | Conference | UNIMAN | "Paediatric organ and effective doses in dental cone beam computed tomography" (C. Theodorakou, WCMPBE) | 7-12 September 2009 | Munich, Germany | Scientific community, civil society, industry | 3,000 | International |
| 18 | Conference | CLUJ | “CBCT assessment of well defined radiolucent jawbone lesion" P 014 (M. Hedesiu, ESHNR) | 1-3 October 2009 | Verona, Italy | Scientific community, civil society, industry | 200 | International |

| NO. | Type of activities[1] | Main leader | Title | Date | Place | Type of audience[2] | Size of audience | Countries addressed |
|---|---|---|---|---|---|---|---|---|
| 19 | Conference | UNIMAN | "Radiation protection considerations for dental cone beam computed tomography equipment" (Anne Walker, IPEM) | 16 December 2009 | Manchester, UK | Scientific community, civil society, industry | 100 | UK |
| 20 | Conference | UNIMAN | Survey of paediatric organ and effective doses in dental CBCT" (C. Theodorakou, IPEM) | 16 December 2009 | Manchester, UK | Scientific community, civil society, industry | 100 | UK |
| 21 | Conference | NKUA | "Development of a Quality Control phantom specifically designed for CBCT" (H. Stamatakis, ECDMFR) | 2-5 June 2010 | Istanbul, Turkey | Scientific community, civil society, industry, policy makers | 250 | Europe |
| 22 | Conference | CLUJ | "CBCT bone quantification for preoperative planning of oral implant placement" (M. Hedesiu, ECDMFR) | 2-5 June 2010 | Istanbul, Turkey | Scientific community, civil society, industry, policy makers | 250 | Europe |
| 23 | Conference | KUL | "Effective dose range for cone beam computed tomography scanners" (R. Pauwels, ECDMFR) | 2-5 June 2010 | Istanbul, Turkey | Scientific community, civil society, industry, policy makers | 250 | Europe |
| 24 | Conference | KUL | "Density and morphology of jaw bone assessed in 2D and 3D imaging methods" (O. Nackaerts, ECDMFR) | 2-5 June 2010 | Istanbul, Turkey | Scientific community, civil society, industry, policy makers | 250 | Europe |
| 25 | Conference | UNIMAN | "Paediatric organ and effective doses in dental cone beam computed tomography" (C. Theodorakou, ECDMFR) | 2-5 June 2010 | Istanbul, Turkey | Scientific community, civil society, industry, policy makers | 250 | Europe |
| 26 | Conference | MAHOD | "A model for cost-analysis of diagnostic methods in oral health care. An application comparing a new imaging technology with a conventional one for maxillary canines with eruption disturbances " (H. Christell, ECDMFR) | 2-5 June 2010 | Istanbul, Turkey | Scientific community, civil society, industry, policy makers | 250 | Europe |
| 27 | Conference | MAHOD | "Evidence of Cost-Analysis on Diagnostic Imaging Methods in Oral Health Care is Insufficient. A Systematic Review" (M. Rohlin, ECDMFR) | 2-5 June 2010 | Istanbul, Turkey | Scientific community, civil society, industry, policy makers | 250 | Europe |
| 28 | Conference | UNIMAN | "A survey of scattered radiation in the vicinity of dental cone beam computed tomography equipment" (L. Sweetman, Medical Physics and Engineering Conference) | 15 September 2010 | Nottingham, UK | Scientific community, civil society, industry | 500 | UK |

| NO. | Type of activities[1] | Main leader | Title | Date | Place | Type of audience[2] | Size of audience | Countries addressed |
|---|---|---|---|---|---|---|---|---|
| 29 | Conference | KUL | "Segmentation of trabecular jaw bone on CBCT and µCT datasets" (O. Nackaerts, Skyscan user meeting). Proceedings book pages 254-256, ISBN 9789081678100 | 12-15 April 2011 | Leuven, Belgium | Scientific community, civil society, industry | 100 | International |
| 30 | Conference | KUL | "A comparison of six CBCT systems for the detection of simulated canine impaction-induced external root resorption in maxillary lateral incisors" (A. Alquerban, American Association of Orthodontics) | 13-17 May 2011 | Chicago, USA | Scientific community, civil society, industry | 450 | International |
| 31 | Conference | KUL | "Dose distribution for CBCT and its implication for defining a dose index" (R. Pauwels, ICDMFR) | 25 – 29 May 2011 | Hiroshima, Japan | Scientific community, civil society, industry, policy makers | 450 | International |
| 32 | Conference | KUL | "Pre-surgical assessment of impacted canines using 2D and 3D imaging" (O. Nackaerts, ICDMFR) | 25 – 29 May 2011 | Hiroshima, Japan | Scientific community, civil society, industry, policy makers | 450 | International |
| 33 | Conference | MAHOD | "Cost evaluation of CBCT imaging in oral health care with examples of SEDENTEXCT" (M. Rohlin, keynote speaker, ICDMFR) | 25 – 29 May 2011 | Hiroshima, Japan | Scientific community, civil society, industry, policy makers | 450 | International |
| 34 | Conference | KUL | "The influence of exposure parameters on jaw bone model accuracy" (B. Vandenberghe, ICDMFR). Second prize in IADMFR research award | 25 – 29 May 2011 | Hiroshima, Japan | Scientific community, civil society, industry, policy makers | 450 | International |
| 35 | Conference | KUL | “Dosimetry and image quality of Cone Beam Computed Tomography in dentistry” (R. Pauwels, invited speaker, Brazilian Dentomaxillofacial Meeting) | 19-22 October 2011 | Salvador, Brazil | Scientific community, civil society | 500 | International |
| 36 | Publication | UNIMAN | SEDENTEXCT Newsletter No. 1 | July 2008 | N/A | Civil society, scientific community, industry, policy makers | 75,000 | Europe |
| 37 | Publication | UNIMAN | "Euratom Project on Dental Cone Beam CT" (in *European Medical Physics News*) | Winter 2008 | N/A | Civil society, scientific community, industry | 2,500 | Europe |
| 38 | Publication | UNIMAN | SEDENTEXCT Newsletter No. 2 | January 2009 | N/A | Civil society, scientific community, industry, policy makers | 75,000 | Europe |
| 39 | Publication | UNIMAN | 'SEDENTEXCT' in ‘Euratom FP7 Research and Training Projects’ volume 1, European Commission, 32-33. | 2009 | N/A | Scientific community, industry, policy makers | 1,000 | Europe |

| NO. | Type of activities[1] | Main leader | Title | Date | Place | Type of audience[2] | Size of audience | Countries addressed |
|---|---|---|---|---|---|---|---|---|
| 40 | Publication | MAHOD | Lecture on Provisional Guidelines to the 45th Annual Swedish Dental Congress summarised in The Journal of the Swedish Dental Association, 2009;14 | 2009 | N/A | Scientific community, civil society, industry | 8,000 | Sweden |
| 41 | Publication | UNIMAN | SEDENTEXCT Newsletter No. 3 | July 2009 | N/A | Scientific community, civil society, industry, policy makers | 75,000 | Europe |
| 42. | Publication | CLUJ | “Recomandari provizorii privind utilizarea tomografiei volumetrice dentare (Cone beam computed tomography – CBCT) in medicina dentara” (M. Hedesiu, CMDR newsletter) | December 2009 | N/A | Scientific community, civil society, industry, policy makers | 1,000 | Romania |
| 43 | Publication | KUL | Proceedings edited by Claude Hodez and Pierre Bravetti: L’imagerie par faisceau conique “cone beam” (Sauramps Médical, Paris, March 2010) including Imagerie dento-maxillaire et cone beam: un nouveau regard à Louvain by Reinhilde Jacobs, pp143-158 | 2010 | N/A | Scientific community, civil society, industry | 500 | France, Belgium |
| 44 | Publication | MAHOD | Lecture on Evidence for CBCT examinations on the 46th Annual Swedish Dental Congress l Congress summarised in The Journal of the Swedish Dental Association, 2010 | 2010 | N/A | Scientific community, civil society, industry | 8,000 | Sweden |
| 45 | Publication | CLUJ | Short version of the Provisional Guidelines in “Buletinul informativ al medicilor dentisti” nr. 3-4/2009, ISSN: 1844-220X | January 2010 | N/A | Scientific community, civil society, industry | 1,200 | Romania |
| 46 | Publication | UNIMAN | SEDENTEXCT Newsletter No. 4 | January 2010 | N/A | Scientific community, civil society, industry, policy makers | 75,000 | Europe |
| 47 | Publication | UNIMAN | SEDENTEXCT Newsletter No. 5 | July 2010 | N/A | Scientific community, civil society, industry, policy makers | 75,000 | Europe |
| 48 | Publication | UNIMAN | SEDENTEXCT provisional guidelines discussed in the editorial of the *American Journal of Orthodontics and Dentofacial Orthopedics* "Clinical guidelines and the use of cone-beam computed tomography" (D. Turpin, AJODO 2010;138:1-2, doi:10.1016/j.ajodo.2010.05.007) | July 2010 | N/A | Scientific community, civil society | 15,000 | International |

| NO. | Type of activities[1] | Main leader | Title | Date | Place | Type of audience[2] | Size of audience | Countries addressed |
|---|---|---|---|---|---|---|---|---|
| 49 | Publication | UNIMAN | SEDENTEXCT Newsletter No. 6 | December 2010 | N/A | Scientific community, civil society, industry, policy makers | 75,000 | Europe |
| 50 | Publication | UNIMAN | EADMFR Newsletter Issue 7 Spring 2011 refers to SEDENTEXCT in its editorial and other articles, including an article by Keith Horner "SEDENTEXCT Report" | Spring 2011 | N/A | Scientific community, civil society | 350 | International |
| 51 | Publication | UNIMAN | "Estimation of paediatric organ and effective doses from dental cone beam computed tomography using anthropomorphic phantoms" (C. Theodorakou), accepted for publication in *British Journal of Radiology* | 2011 | N/A | Scientific community, civil society | 1,000 | International |
| 52 | Publication | KUL | " A comparison of six CBCT systems for the detection of simulated canine impaction-induced external root resorption in maxillary lateral incisors" (A. Alqerban), accepted for publication in *American Journal of Orthodontics* | 2011 | N/A | Scientific community, civil society | 1,000 | International |
| 53 | Publication | KUL | " Development and applicability of a quality control phantom for dental cone beam CT" (R. Pauwels), accepted for publication in *Journal of Applied Clinical Medical Physics* | 2011 | N/A | Scientific community, civil society | 1,000 | International |
| 54 | Publication | MAHOD | “A framework for costing diagnostic methods in oral health care. An application comparing a new imaging technology with the conventional approach for maxillary canines with eruption disturbances” (H. Christell et al. ) submitted to CDOE (Community Dentistry and Oral Epidemiology) | 2011 | N/A | Scientific community, civil society | 1,000 | International |
| 55 | Publication | MAHOD | “Variation in costs of CBCT-examinations among health care systems” (H. Christell et al) submitted to DMFR DentoMaxilloFacial Radiology) | 2011 | N/A | Scientific community, civil society | 1,000 | International |
| 56 | Publication | KUL | “Dose distribution for dental cone beam CT and its implication for defining a dose index” (R. Pauwels et al.) submitted to *DentoMaxilloFacial Radiology* (DMFR) | 2011 | N/A | Scientific community, civil society | 1,000 | International |
| 57 | Publication | CLUJ | "Is CBCT justified in oral implant treatment? Comparative study between 2D and 3D implant planning" (M. Hedesiu) submitted to *Journal of Oral Rehabilitation* | 2011 | N/A | Scientific community, civil society | 1,000 | International |

| NO. | Type of activities[1] | Main leader | Title | Date | Place | Type of audience[2] | Size of audience | Countries addressed |
|---|---|---|---|---|---|---|---|---|
| 58 | Publication | CLUJ | "Comparison of different CBCT scans and protocols for the detection of simulated apical bone lesions" (M. Hedesiu) submitted to *DentoMaxilloFacial Radiology* (DMFR) | 2011 | N/A | Scientific community, civil society | 1,000 | International |
| 59 | Publication | UNIMAN | “An analysis of training needs for continuing professional development in cone beam CT” (H. Devlin et al), in preparation for DMFR (DentoMaxilloFacial Radiology) | 2011 | N/A | Scientific community, civil society | 1,000 | International |
| 60 | Publication | MAHOD | “Economic evaluation in oral health care with emphasis on diagnostic methods. A systematic literature review” (H. Christell et al), in preparation for CDOE (Community Dentistry and Oral Epidemiology) | 2011 | N/A | Scientific community, civil society | 1,000 | International |
| 61 | Publication | MAHOD | “Observer performance and confidence in assessing radiographs from conventional methods compared with CBCT images for maxillary canines with eruption disturbances” (C. Lindh et al) in preparation for *Journal of Orthodontics* | 2011 | N/A | Scientific community, civil society | 1,000 | International |
| 62 | Publication | UNIMAN | "A systematic review of the effectiveness of CBCT in the identification of caries lesions" (V. Rushton et al) in preparation for *Journal of Dentistry* | 2011 | N/A | Scientific community, civil society | 1,000 | International |
| 63 | Publication | UNIMAN | "A systematic review of the effectiveness of CBCT in the identification of periodontal disease" (V. Rushton et al) in preparation for *Journal of Dentistry* | 2011 | N/A | Scientific community, civil society | 1,000 | International |
| 64 | Publication | UNIMAN | “Effective dose conversion factors for dental cone beam computed tomography” (C. Theodorakou et al) in preparation for *Physics in Medicine and Biology* | 2011 | N/A | Scientific community, civil society | 1,000 | International |
| 65 | Publication | UNIMAN | “A survey of scattered radiation in the vicinity of dental cone beam tomography - requirements for shielding”, (L. Sweetman et al.) in preparation for *Journal of Radiological Protection* | 2011 | N/A | Scientific community, civil society | 1,000 | International |
| 66 | Publication | NKUA | “Modification of a Quality Control CT phantom for using with dental CBCT” (K. Tsiklakis et al) in preparation for *British Journal of Radiology* (BJR) | 2011 | N/A | Scientific community, civil society | 1,000 | International |

| NO. | Type of activities[1] | Main leader | Title | Date | Place | Type of audience[2] | Size of audience | Countries addressed |
|---|---|---|---|---|---|---|---|---|
| 67 | Publication | NKUA | "The use of a specifically developed CBCT quality control phantom for examining the correlation between CBCT pixel intensity values and medical CT numbers" (K. Tsiklakis et al), in preparation for *DentoMaxillofacial Radiology* (DMFR) | 2011 | N/A | Scientific community, civil society | 1,000 | International |
| 68 | Publication | NKUA | "Development of a quality assurance protocol for dental Cone Beam CT" (K. Tsiklakis et al) in preparation for *DentoMaxillofacial Radiology* (DMFR) | 2011 | N/A | Scientific community, civil society | 1,000 | International |
| 69 | Publication | KUL | "Dose optimization in CBCT through field of view limitation and half-scanning" (R. Pauwels et al.), in preparation for *DentoMaxilloFacial Radiology* (DMFR) | 2011 | N/A | Scientific community, civil society | 1,000 | International |
| 70 | Publication | KUL | "Validation of a standardized CBCT dose index and conversion to effective dose" (R. Pauwels et al.) in preparation for *European Journal of Radiology* | 2011 | N/A | Scientific community, civil society | 1,000 | International |
| 71 | Publication | KUL | "In vivo skin dose for CBCT" (R. Pauwels et al) in preparation, journal not yet decided. | 2011 | N/A | Scientific community, civil society | 1,000 | International |
| 72 | Publication | KUL | "Quantification of metal artifacts on cone-beam computed tomography images" (R. Pauwels et al.), in preparation for *Clinical Oral Implants Research* | 2011 | N/A | Scientific community, civil society | 1,000 | International |
| 73 | Publication | KUL | "Spatial and contrast resolution of CBCT devices: an observer study" (R. Pauwels et al.), in preparation for *Oral Surgery, Oral Medicine, Oral Pathology, Oral Radiology and Endodontology* (OOOOE) | 2011 | N/A | Scientific community, civil society | 1,000 | International |
| 74 | Publication | KUL | "Contrast, noise and uniformity of CBCT" (R. Pauwels et al.), in preparation, journal not yet decided | 2011 | N/A | Scientific community, civil society | 1,000 | International |
| 75 | Publication | KUL | "Correlation between CBCT voxel values and CT numbers" (R. Pauwels et al) in preparation for *Clinical Oral Implants Research* | 2011 | N/A | Scientific community, civil society | 1,000 | International |
| 76 | Publication | KUL | "Neurosensory disturbances following impacted wisdom tooth removal based on 2D and 3D imaging: a pilot study" in preparation for JOr | 2011 | N/A | Scientific community, civil society | 1,000 | International |
| 77 | Publication | CLUJ | "Pre-surgical assessment and postoperative follow-up of sinus grafting procedures using cone-beam computed | 2011 | N/A | Scientific community, civil society | 1,000 | International |

| NO. | Type of activities[1] | Main leader | Title | Date | Place | Type of audience[2] | Size of audience | Countries addressed |
|---|---|---|---|---|---|---|---|---|
| | | | tomography (CBCT) compared with panoramic radiographs" (M. Baciut et al) in preparation for *Clinical Oral Implant Journal* | | | | | |
| 78 | Press release | UNIMAN | Joint press release with EADMFR concerning Basic Principles | February 2009 | N/A | Civil society, scientific community, industry, policy makers | 75,000 | Europe |
| 79 | Articles published in popular press | UNIMAN | "Radiation worries for children in dentists' chairs" (New York Times) | 22 November 2010 | N/A | Civil society | 900,000 | USA, international |
| 80 | Articles published in popular press | LTO | UK distributor MediScientific advertises SedentexCT in RAD magazine. | February 2011 | N/A | Scientific community, civil society, industry, policy makers | 18,000 | UK |
| 81 | Exhibitions | LTO | Leeds Test Objects exhibits the SedentexCT phantoms at the European Congress of Radiology 2011 (Vienna) | 4-8 March 2011 | Vienna, Austria | Scientific community, civil society, industry, policy makers | 20,000 | Europe |
| 82 | Exhibitions | LTO | UK distributor MediScientific exhibits SEDENTEXCT phantom at BSDMFR Leeds, UK. | 31 March 2011 | Leeds, UK | Scientific community, civil society, industry, policy makers | 100 | Europe |
| 83. | Flyer | LTO | Leeds Test Objects' February newsletter informs distributors of release of SedentexCT phantoms. | February 2011 | N/A | Industry | 50 | International |
| 84 | Flyer | LTO | Leeds Test Objects send a mail shot to CBCT device manufacturers. | January 2011 | N/A | Scientific community, civil society, industry, policy makers | 30 | International |
| 85 | Presentation | UNIMAN | "Update on SEDENTEXCT Project" (Anne Walker, The Christie Hospital) | 26 February 2008 | Manchester, UK | Scientific community, civil society, industry | 20 | UK |
| 86 | Presentation | VU | "Possibility for dosimetry in Lithuania" (J. Ziliukas, SEDENTEXCT Physics Group) | 9 June 2008 | Leuven, Belgium | Scientific community | 10 | Europe |
| 87 | Presentation | NKUA | "Current position on CBCT licensing and training in Europe" (K. Tsiklakis, ECDMFR) | 25-28 June 2008 | Budapest, Hungary | Scientific community, civil society, industry, policy makers | 250 | Europe |
| 88 | Presentation | UNIMAN | "The SEDENTEXCT project" (Anne Walker, to colleagues on research committee at North West Medical Physics) | 1 July 2008 | Manchester, UK | Scientific community, civil society | 20 | UK |

| NO. | Type of activities[1] | Main leader | Title | Date | Place | Type of audience[2] | Size of audience | Countries addressed |
|---|---|---|---|---|---|---|---|---|
| 89 | Presentation | MAHOD | "SEDENTEXCT – description of project"(C. Lindh, to colleagues in Malmö Dental School) | 20 August 2008 | Malmö, Sweden | Scientific community, civil society | 20 | Sweden |
| 90 | Presentation | UNIMAN | "CBCT Applications and Selection Criteria" (K. Horner, BSDMFR) | 26 September 2008 | London, UK | Scientific community, civil society, industry | 150 | UK |
| 91 | Presentation | NKUA | "CBCT or Dental Volumetric Tomography" (K. Tsiklakis, 28th Panhellenic Dental Conference) | 23-26 October 2008 | Thessaloniki, Greece | Scientific community, civil society, industry | 300 | Greece |
| 92 | Presentation | UNIMAN | "The use of cone beam computed tomography" (V. Rushton, University of Warwick) | 28 October 2008 | Coventry, UK | Scientific community, civil society | 10 | UK |
| 93 | Presentation | NKUA | "Imaging of Benign and Malignant tumors of the jaws" (K. Tsiklakis, AAOMR) | 29 October – 1 November 2008 | Pittsburgh, USA | Scientific community, civil society, industry | 200 | International |
| 94 | Presentation | NKUA | "Round table on CBCT. Basic Principles and dosimetry" (K. Tsiklakis, 11th Panhellenic Congress of the Greek Orthodontic Society) | 6-7 December 2008 | Athens, Greece | Scientific community, civil society, industry | 250 | Greece |
| 95 | Presentation | MAHOD | Presentations to different groups of clinicians in order to recruit patients more actively | Jan-Mar 2009 | Malmö, Sweden | Scientific community, civil society | 20 | Sweden |
| 96 | Presentation | UNIMAN | Dissemination of SEDENTEXCT Provisional Guidelines to Implantology MSc students, University of Warwick | September 2009 | Coventry, UK | Civil society | 10 | UK |
| 97 | Presentation | KUL | Looking to teeth & jaws in depth: CBCT in dentistry (R Jacobs, JABRO) | 3-5 September 2009 | Ouro Preto, Brazil | Scientific community, civil society, industry | 100 | International |
| 98 | Presentation | KUL | "The impact of CBCT on diagnosis and therapy in oral health care (R Jacobs, WCMPBE) | 7-12 September 2009 | Munich, Germany | Scientific community, civil society, industry | 200 | International |
| 99 | Presentation | KUL | "Patient risk factors/patient assessment (including radiographic assessment) (R Jacobs, Implant guidelines meeting – Belgian Society of Periodontology) | 16 October 2009 | Leuven, Belgium | Scientific community, civil society, industry | 150 | Belgium |
| 100 | Presentation | CLUJ | CBCT preliminary recommendation for use in dental radiology, oral presentation (M. Hedesiu, International Congress of dentistry, NAOPCABIODENT and Symposium of Oral and Maxillofacial Radiology) | 5-7 November 2009 | Cluj-Napoca, Romania | Scientific community, civil society, industry | 50 | International |
| 101 | Presentation | MAHOD | "Evidence of new methods – in a European perspective" (C. Lindh, 45th Annual Swedish Dental Congress) | 12-14 November 2009 | Stockholm, Sweden | Scientific community, civil society, industry | 25 | Sweden |

| NO. | Type of activities[1] | Main leader | Title | Date | Place | Type of audience[2] | Size of audience | Countries addressed |
|---|---|---|---|---|---|---|---|---|
| 102 | Presentation | UNIMAN | “Developments in Dental Radiology – a Clinical Perspective” (K. Horner, IPEM) | 16 December 2009 | Manchester, UK | Scientific community, civil society, industry | 75 | UK |
| 103 | Presentation | KUL | "Imagerie dento-maxillaire et cone beam: un nouveau regard à Louvain" (R. Jacobs, conference: L’imagerie par faisceau conique “cone beam” ) | 13 March 2010 | Nancy, France | Scientific community, civil society, industry | 200 | France, Belgium |
| 104 | Presentation | UNIMAN | “Imaging for implants”, lecture to MSc students in Dental Implantology, University of Manchester (K. Horner) | 15 March 2010 | Manchester, UK | Civil society | 20 | UK |
| 105 | Presentation | UNIMAN | “Imaging for implants”, lecture to MSc students in Dental Implantology, University of Central Lancashire (K. Horner) | 18 March 2010 | Manchester, UK | Civil society | 20 | UK |
| 106 | Presentation | KUL | "In the depth of teeth, is cone beam CT improving endodontics or rather promoting implant surgery" (R. Jacobs, National Dental Congress and ARE 2010 Romanian Association Endodontics) | 24-28 March 2010 | Craiova, Romania | Scientific community, civil society, industry | 200 | Romania |
| 107 | Presentation | CLUJ | Dissemination of Training Module 10, "Interpretation of CBCT images" (M. Baciut, EACMFS Course) | 16-17 April 2010 | Constanta, Romania | Scientific community, civil society, industry | 250 | Romania |
| 108 | Presentation | KUL | "La dosimétrie sera-t-elle un frein au passage à la 3D?" (R. Jacobs, 56th Conference of the Société Francophone de Médecine Buccale et de Chirurgie Buccale | 22-24 April 2010 | Nîmes, France | Scientific community, civil society, industry | 100 | France, Belgium |
| 109 | Presentation | MAHOD | "Cost-effectiveness of CBCT" disseminated to organisation of Swedish dentists in Germany | 7-9 June 2010 | La Wantzenau, France | Scientific community, civil society, industry | 50 | Germany, Sweden |
| 110 | Presentation | VU | “CBCT in endodontology: assessment of periapical tissue, diagnosis of root fracture” (D. Ivanauskaite, Endodontology 2010) | 26-27 November 2010 | Vilnius, Lithuania | Scientific community, civil society, industry | 250 | Lithuania |
| 111 | Presentation | UNIMAN | “Using CBCT” (Aspects of justification and referral criteria) at the Health Protection Agency training course for dentists. | July 2011 | Chilton, Oxfordshire, UK | Scientific community, civil society | 30 | UK |
| 112 | Presentation | MAHOD | Specialist trainee course "The use of CBCT in different clinical situations" (C. Lindh) | September 2011 | Malmö, Sweden | Scientific community, civil society | 27 | Sweden |
| 113 | Presentation | UNIMAN | “CBCT equipment and performance issues” at the European Workshop to Introduce Radiation Protection 162. | September 2011 | Dublin, Ireland | Policy makers; scientific community | 75 | International |

| NO. | Type of activities[1] | Main leader | Title | Date | Place | Type of audience[2] | Size of audience | Countries addressed |
|---|---|---|---|---|---|---|---|---|
| 114 | Presentation | MAHOD | "The Sedentexct project and specifically Cost-effectiveness of CBCT" (C. Lindh, Swedish Dental Association) | 19 November 2011 | Gothenburg, Sweden | Scientific community, civil society | 40 | Sweden |
| 115 | Presentation | UNIMAN | Co-chair and speaker at European Association of Osseointegration training course for implant dentists on CBCT | October 2012 | Copenhagen, Denmark | Scientific community, civil society | 200 | International |
| 116 | Presentation | MAHOD | Lecture on Evidence for CBCT examinations on the 46th Annual Swedish Dental Congress Nov, 2010 | 19 Nov 2010 | Gothenburg, Sweden | Scientific community, civil society, industry, policy makers | 50 | Sweden |
| 117 | Web | UNIMAN | Short note on UK Medical Physics and Engineering mailbase (Anne Walker) | Summer 2008 | N/A | Scientific community, civil society, industry | 500 | UK |
| 118 | Web | UNIMAN | SEDENTEXCT website – wiki information on CBCT and information for patients became available | 2009 | N/A | Scientific community, industry, civil society, policy makers | <to be completed><br>9999 | International |
| 119 | Web | VU | Collaboration in dose measurement with the Radiation Protection Centre of Lithuania | 2009 | N/A | Policy makers | 20 | Lithuania |
| 120 | Web | VU | Collaboration regarding WPs 2 & 5 with the Zalgirio Clinic of Hospital of Vilnius University | 2009 | N/A | Scientific community, civil society, industry | 50 | Lithuania |
| 121 | Web | UNIMAN | Short note on UK Medical Physics and Engineering mailbase (Anne Walker) | Spring 2009 | N/A | Scientific community, industry | 500 | UK |
| 122 | Web | CLUJ | The Provisional guidelines (English version) were posted on the site of Romanian Dentist Professional Association (CMDR) http://www.cmdr.ro/doc/Noutati/Ghid%20CBCT.pdf | December 2009 | N/A | Scientific community, industry, policy makers | 10,000 | Romania |
| 123 | Web | LTO | Leeds Test Objects' website product pages feature SedentexCT IQ and SedentexCT DI phantoms. | January 2011 | N/A | Scientific community, civil society, industry, policy makers | 425 | International |
| 124 | Web | LTO | UK distributor MediScientific's website product pages feature SedentexCT phantoms. | January 2011 | N/A | Scientific community, civil society, industry, policy makers | 120 | UK |
| 125 | Web (email) | UNIMAN | The 'Basic Principles' guideline document was passed to the Euratom Article 31 Expert Group | November 2008 | N/A | Policy makers | 15 | Europe |

| NO. | Type of activities[1] | Main leader | Title | Date | Place | Type of audience[2] | Size of audience | Countries addressed |
|---|---|---|---|---|---|---|---|---|
| 126 | Web (email) | UNIMAN | Communications with Tomohiro Okano, Director, Showa University Dental Hospital Professor of Radiology, Showa University School of Dentistry, Japan, with a view to translating the Basic Principles document into Japanese | November 2008 | N/A | Scientific community, policy makers | 10 | Japan |
| 127 | Web (email) | UNIMAN | Cooperation with DMFR providing input into German national guidelines on CBCT | 2009 | N/A | Policy makers | 10 | Germany |
| 128 | Web (email) | UNIMAN | Dissemination of Provisional Guidelines to national and international professional organisations in dentistry and medical physics | May 2009 | N/A | Scientific community, civil society, industry | 65,000 | International |
| 129 | Web (email) | UNIMAN | Dissemination of Provisional Guidelines to practising and university dentists and postgraduate students | May 2009 | N/A | Scientific community, civil society | 8,500 | International |
| 130 | Web (email) | UNIMAN | Dissemination of Provisional Guidelines to members of radiation protection organisations | May 2009 | N/A | Policy makers | 500 | International |
| 131 | Web (email) | CLUJ | Dissemination of Provisional Guidelines to CBCT equipment dealers in Romania | May 2009 | Romania | Industry | 5 | Romania |
| 132 | Web (email) | NKUA | Dissemination of WP2 dosimetry and scatter dose to the Greek Atomic Energy Commission (GAEC) | May 2009 | N/A | Policy makers | 10 | Greece |
| 133 | Web (email) | UNIMAN | Simplant email to its UK mailbase "Important information for (CB)CT owners/users" recommending reading SEDENTEXCT Provisional Guidelines and HPA Report on CBCT. | 15 February 2010 | N/A | Scientific community, civil society, industry | 200 | UK |
| 134 | Web (email) | VU | Dissemination of SEDENTEXCT Provisional Guidelines to the Riga Stradins University | 2011 | Riga, Latvia | Scientific community | 100 | Latvia |
| 135 | Web (email) | UNIMAN | Dissemination of SEDENTEXCT Workshop to national and international professional organisations in dentistry and medical physics | 27 January 2011 | N/A | Scientific community, civil society, industry | 65,000 | International |
| 136 | Web (email) | UNIMAN | Dissemination of SEDENTEXCT Workshop to practising and university dentists and postgraduate students | 27 January 2011 | N/A | Scientific community, civil society | 8,500 | International |
| 137 | Web (email) | UNIMAN | Dissemination of SEDENTEXCT Workshop to members of radiation protection organisations | 27 January 2011 | N/A | Policy makers | 500 | International |
| 138 | Web (email) | UNIMAN | Dissemination of SEDENTEXCT Workshop to CBCT equipment manufacturers and dealers | 27 January | N/A | Industry | 20 | International |

| NO. | Type of activities[1] | Main leader | Title | Date | Place | Type of audience[2] | Size of audience | Countries addressed |
|---|---|---|---|---|---|---|---|---|
| | | | | 2011 | | | | |
| 139 | Web (email) | UNIMAN | Communications with WP-MED of EC regarding publication of Definitive Guidelines by Office for Official Publications of EC | June 2011 | N/A | Policy makers | 15 | Europe |
| 140 | Web (email) | UNIMAN | Dissemination of Definitive Guidelines to national and international professional organisations in dentistry and medical physics | 20 June 2011 | N/A | Scientific community, civil society, industry | 65,000 | International |
| 141 | Web (email) | UNIMAN | Dissemination of Definitive Guidelines to practising and university dentists and postgraduate students | 20 June 2011 | N/A | Scientific community, civil society | 8,500 | International |
| 142 | Web (email) | UNIMAN | Dissemination of Definitive Guidelines to members of radiation protection organisations | 20 June 2011 | N/A | Policy makers | 500 | International |
| 143 | Web (email) | UNIMAN | Dissemination of Definitive Guidelines to CBCT equipment manufacturers and dealers | 20 June 2011 | N/A | Industry | 20 | International |
| 144 | Workshop | UNIMAN | K. Horner and A. Walker were members of the UK Health Protection Agency's Working Group on Dental Cone Beam CT | September 2008 - 2009 | N/A | Policy makers | 20 | UK |
| 145 | Workshop | KUL | Collaboration with a project at KUL on a voxel model for CBCT simulation studies | 2008 -2011 | Leuven, Belgium | Scientific community | 50 | Belgium |
| 146 | Workshop | CLUJ | Collaboration with project CNCSIS 146/2007 | 2008-2011 | Cluj-Napoca, Romania | Scientific community | 6 | Romania |
| 147 | Workshop | CLUJ | Collaboration with project ' Imaging Laboratory for Maxillofacial Surgery' (CNCSIS no. 155/2006) | 2008-2011 | Cluj-Napoca, Romania | Scientific community | 50 | Romania |
| 148 | Workshop | CLUJ | Collaboration with project 'STEMCELLS' (CEEX 2005. PC-D01-PT11-39) | 2008-2011 | Cluj-Napoca, Romania | Scientific community | 20 | Romania |
| 149 | Workshop | CLUJ | Collaboration with project 'CMDIAGNOSIS' (CEEX 2006) | 2008-2011 | Cluj-Napoca, Romania | Scientific community | 10 | Romania |
| 150 | Workshop | UNIMAN | Discussion with executive members of EADMFR about closer links between both organisations' websites | September 2010 | Spain | Policy makers | 15 | Europe |
| 151 | Press release | UNIMAN | Press release regarding Definitive Guidelines (planned) | September 2011 | N/A | Scientific community, civil society, industry, policy makers, media | 9999 | International |

## Section B

| Type of Exploitable Foreground[1] | Description of exploitable foreground | Confidential Click on YES/NO | Foreseen embargo date dd/mm/yyyy | Exploitable product(s) or measure(s) | Sector(s) of application[2] | Timetable, commercial or any other use | Patents or other IPR exploitation (licences) | Owner & Other Beneficiary(s) involved |
|---|---|---|---|---|---|---|---|---|
| EXPLOITATION VIA STANDARDS | BASIC PRINCIPLES | NO | NA | CONSENSUS GUIDELINES | MEDICAL Q86.1.0, Q86.2.3 | 2009 | NONE PLANNED | UNIMAN<br><br>[COPYRIGHT OF TEXT OF PUBLISHED PAPER TRANSFERRED TO PUBLISHERS: BRITISH INSTITUTE OF RADIOLOGY] |
| EXPLOITATION VIA STANDARDS, EXPLOITATION VIA EU POLICIES | GUIDELINES | NO | NA | EVIDENCE-BASED GUIDELINES | MEDICAL Q86.1.0, Q86.2.3 | 2011 | NONE PLANNED | UNIMAN, NKUA, UMFCLUJ, KUL, MAHOD, VU. |
| GENERAL ADVANCEMENT OF KNOWLEDGE | STUDY RESULTS ON CLINICAL APPLICATIONS OF CBCT | NO | NA | STUDY RESULTS AND METHODOLOGICAL CONSIDERATIONS | MEDICAL, POLICY Q86.1.0, Q86.2.3 | NOT YET SPECIFIED | NONE PLANNED | UNIMAN, NKUA, UMFCLUJ, KUL, MAHOD, VU. |
| EXPLOITATION VIA STANDARDS | QA MANUAL | NO | NA | QA PROCEDURES | 1.MEDICAL/DENTAL<br>2. CBCT EQUIPMENT PHYSICIST INSPECTION<br>Q86.1.0, Q86.2.3 | 2011 | NONE PLANNED | UNIMAN |
| GENERAL ADVANCEMENT OF KNOWLEDGE | IMAGE ANALYSIS RESULTS ON CBCT | NO | NA | RESULTS ON IMAGE ANALYSIS FOR DIFFERENT IMAGE QUALITY | ALL USES OF CBCT M72.1.9 | NOT YET SPECIFIED | NONE PLANNED | UNIMAN, NKUA, UMFCLUJ, KUL, MAHOD, VU. |

[19] A drop down list allows choosing the type of foreground: General advancement of knowledge, Commercial exploitation of R&D results, Exploitation of R&D results via standards, exploitation of results through EU policies, exploitation of results through (social) innovation.
[2] A drop down list allows choosing the type sector (NACE nomenclature) : http://ec.europa.eu/competition/mergers/cases/index/nace_all.html

| Type of Exploitable Foreground[1] | Description of exploitable foreground | Confidential Click on YES/NO | Foreseen embargo date dd/mm/yyyy | Exploitable product(s) or measure(s) | Sector(s) of application[2] | Timetable, commercial or any other use | Patents or other IPR exploitation (licences) | Owner & Other Beneficiary(s) involved |
|---|---|---|---|---|---|---|---|---|
| | | | | PARAMETERS | | | | |
| GENERAL ADVANCEMENT OF KNOWLEDGE | DOSE INDEX DEFINITIONS AND CONVERSION FACTORS | NO | NA | THREE POTENTIAL DOSE INDICES AND CONVERSION FACTORS TO PATIENT DOSE | ALL USES OF CBCT M72.1.9 | NOT YET SPECIFIED | NONE PLANNED | KUL, UNIMAN |
| GENERAL ADVANCEMENT OF KNOWLEDGE | DOSE MEASUREMENT RESULTS | NO | NA | ALL DOSE MEASUREMENTS (DOSE INDEX, EFFECTIVE DOSE, IN VIVO DOSE) | ALL USES OF CBCT M72.1.9 | NOT YET SPECIFIED | NONE PLANNED | KUL, UNIMAN, NKUA, MAHOD, VU. |
| GENERAL ADVANCEMENT OF KNOWLEDGE | SURFACE SEGMENTATIO N | NO | NA | SURFACE SEGMENTATION: EXPOSURE PARAMETERS X CBCT DEVICES X JAW TYPE | CBCT-BASED SURGICAL PLANNING: IMPLANTOLOGY, ORTHODONTICS M72.1.9 | NOT YET SPECIFIED | NONE PLANNED | KUL |
| GENERAL ADVANCEMENT OF KNOWLEDGE | TRABECULAR BONE SEGMENTATIO N | NO | NA | TRABECULAR BONE SEGMENTATION: CBCT DEVICES X JAW TYPE X BONE QUALITY | GENERAL DENTISTRY, PERIODONTOLOGY, ORAL SURGERY M72.1.9 | NOT YET SPECIFIED | NONE PLANNED | KUL |
| GENERAL ADVANCEMENT OF KNOWLEDGE | HEALTH ECONOMICS METHODOLOGY | YES | 2013 | METHODOLOGY FOR ASSESSING EFFECTIVENESS OF DENTAL CBCT | M72.1.9 | NOT YET SPECIFIED | NONE PLANNED | MAHOD, UNIMAN |
| GENERAL ADVANCEMENT OF KNOWLEDGE | WEBSITE | NO | NOT YET KNOWN | INFORMATION RESOURCES ON CBCT | GENERAL DENTISTRY P85.4, P85.5 | 2011 | NONE PLANNED | UNIMAN, NKUA, UMFCLUJ, LTO, KUL, MAHOD, VU. |
| | | | | | | | | |

## Basic Principles

*Purpose:*
The 'Basic Principles' provide a consensus-based framework for the development of basic standards for clinical use of dental CBCT, and can be used as a basis for developing operational guidelines on the use of dental CBCT.

*How the foreground might be exploited, when and by whom:*
The Basic Principles can be referenced in other documents, papers etc, by scientists, clinicians and regulatory authorities, with no time limit.

*IPR exploitable measures taken or intended:*
No IPR measures have been taken or are intended. The text of the paper published on the development of these guidelines (Horner K et al. Basic Principles for Use of Dental Cone Beam CT: Consensus Guidelines of the European Academy of Dental and Maxillofacial Radiology. Dentomaxillofacial Radiology 2009; 38: 187-195) has been transferred to publisher.

*Further research necessary, if any:*
None.

*Potential / expected impact (quantify where possible):*
The Basic Principles can be incorporated into national and international guideline and standards documents. This has already been achieved for the Norwegian, Belgian, French and UK Guideline documents.

## Guidelines

*Purpose:*
The SEDENTEXCT evidence-based guidelines on the clinical use of CBCT in dentistry include referral criteria, quality assurance guidelines and optimisation strategies, so provide strategic and operational guidance on best practice in the use of CBCT.

*How the foreground might be exploited, when and by whom:*

The Guidelines (in whole or in part) can be reproduced in other documents, papers etc, by scientists, clinicians and regulatory authorities over the next five years.

*IPR exploitable measures taken or intended:*
No IPR measures have been taken or are intended.

*Further research necessary, if any:*
No further research is required at present. The guidelines will be revised after no longer than five years. The current intention is that this will be led by the European Academy of Dental and Maxillofacial Radiology.

*Potential / expected impact (quantify where possible):*
The SEDENTEXCT Guidelines can be incorporated into national and international guideline and standard documents, which will lead to improvements in the health of European and worldwide citizens undergoing CBCT examinations. The Guidelines are expected to be used in undergraduate, postgraduate and continuing education of dentists in Europe and beyond, to propagate best practice. The SEDENTEXCT Provisional Guidelines (2009) were referenced in national guidelines in Norway, Belgium and UK. It is likely that the Definitive Guidelines (2011) will be similarly influential. Agreement has been reached to allow translation into Portuguese by colleagues in Brazil.

**Study results on clinical applications of CBCT**

*Purpose:*
The purpose of exploiting the results on clinical applications of CBCT is to provide reference works on diagnostic efficacy of CBCT in dentomaxillofacial applications.

*How the foreground might be exploited, when and by whom:*
Results from the clinical studies contributed to the SEDENTEXCT Guidelines and thus will be helpful to clinicians consulting the Guidelines and policy makers developing related guidelines.

*IPR exploitable measures taken or intended:*
None

*Further research necessary, if any:*
Research in this field will continue to be necessary, as methodological and ethical challenges will remain present.

*Potential / expected impact (quantify where possible):*
Impact can be defined as the optimised use of CBCT for specific clinical applications.

**QA Manual**

*Purpose:*
The QA Manual provides the user and the dental and medical physics community with the basic quality assurance principles and methods for dental CBCT systems.

*How the foreground might be exploited, when and by whom:*

The QA Manual already accompanies the LTO quality control phantom and has been included in the SEDENTEXCT Guidelines document.

*IPR exploitable measures taken or intended:*
Open access

*Further research necessary, if any:*
Further work is needed to collect and analyse quality assurance data from centres across Europe, to set baselines for acceptable performance of CBCT devices and to optimise the QA protocols.

*Potential / expected impact (quantify where possible):*

The use of the QA Manual will lead to optimised performance of dental CBCT systems and optimised radiation doses for patients and staff. Content will influence decision on Suspension levels for CBCT being addressed currently (RP162) by the European Commission.

**Image analysis results on CBCT**

*Purpose:*
The image analysis results from the SEDENTEXCT project increase the knowledge of the performance range of CBCT devices for different technical image quality parameters.

*How the foreground might be exploited, when and by whom:*
Researchers and manufacturers can use the image analysis results obtained from the range of CBCT devices and protocols used in SEDENTEXCT to continue research and development on image quality optimisation.

*IPR exploitable measures taken or intended:*
No IPR measures have been taken or are intended.

*Further research necessary, if any:*
Using the SEDENTEXCT quality control phantom, new measurements can be obtained from any new device or protocol, and results can directly be compared to previously obtained measurements.

*Potential / expected impact (quantify where possible):*
The work is expected to lead to standardized measurement of image quality on CBCT, definition of different optimisation strategies, and quantification of improvement of image quality through exposure adjustment or reconstruction.

**Dose index definitions and conversion factors**

*Purpose:*
The dose index definitions and conversion factors facilitate routine monitoring of the dose output from a CBCT device, to identify any deviations. By using an index that can be related to patient risk, an estimate can be made of the effective dose received by typical adult and paediatric patients.

*How the foreground might be exploited, when and by whom:*
Manufacturers and medical physicists can use a dose index measured in a standardized way, and use this index to estimate patient risk from a certain CBCT protocol. Manufacturers, medical physicists and dental professionals can use the conversion factors to estimate the effective dose to a typical adult or paediatric patient for their dental CBCT machine.

*IPR exploitable measures taken or intended:*
No IPR measures have been taken or are intended.

*Further research necessary, if any:*
Further research would be required to update the conversion factors and dose indices for new dental CBCT machines.

*Potential / expected impact (quantify where possible):*
It will become much more straightforward to compare CBCT exposure protocols when a standardised index is used. This facilitates dose optimisation as the effect of certain dose reduction strategies can be quantified using routine measurements, rather than requiring tedious effective dose measurements. The risk to a typical patient could be estimated and optimisation techniques could be developed.

**Dose measurement results**

*Purpose:*
The dose measurement results increase general knowledge of the dose range in CBCT imaging, and enable clear and evidence-based definitions of dose optimisation strategies.

*How the foreground might be exploited, when and by whom:*
CBCT users, researchers and manufacturers can use the information obtained from these measurements. A clear understanding of the dose ranges obtained with CBCT imaging, the factors that influence this dose, and how to reduce it in practice can lead to a more optimised use of CBCT in terms of dose reduction.

*IPR exploitable measures taken or intended:*
No IPR measures have been taken or are intended.

*Further research necessary, if any:*
No further research is required.

*Potential / expected impact (quantify where possible):*
The work is expected to lead to a significant reduction in x-ray doses from CBCT imaging.

**Surface segmentation**

*Purpose:*
The purpose of surface segmentation is to provide models for CBCT-based surgical planning. Its main applicability will be the planning of implant placement.

*How the foreground might be exploited, when and by whom:*
The present studies are the first to show and determine a critical exposure parameter setup for each CBCT device regarding segmentation accuracy enabling to make guidelines and recommendations on machine and software settings. These findings are useful for both CBCT companies, third party software providers and dentists using these products. On the basis of the outcome of present surface segmentation studies, companies specialising in CBCT-based surgical planning software and/or CBCT manufacturers may integrate guidelines and protocols for their customers on how to set the optimal exposure parameters for a specific CBCT scan of either an upper or lower jaw. This will be published and thus made publicly available.

*IPR exploitable measures taken or intended:*
No IPR measures have been taken or are intended.

*Further research necessary, if any:*
The present surface segmentation study might be elaborated to provide data based on larger datasets. This would be research aiming at defining imaging standards for specific applications and equipment.

*Potential / expected impact (quantify where possible):*
The impact can be defined as optimised use of CBCT for specific clinical applications.

**Trabecular bone segmentation**

*Purpose:*
The purpose of trabecular bone segmentation is to provide objective measures of bone quality. Its main applicability will be the planning of implant placement, assessment of periodontal tissues and follow-up of bone lesions such as osteonecrosis, bone tumours, etc.

*How the foreground might be exploited, when and by whom:*
The present study is the first on finding a possibility for quantifying bone quality on dental CBCT, as other measures developed for CT or 2D methods do not seem to readily apply. These findings are therefore useful for CBCT companies who can try and adapt their machines and software to enable reliable bone quantification.  It may also be useful for third party software providers making implant planning software, enabling them to integrated customized tools for CBCT bone quality assessment in their software.  Finally dentists may benefit from using the hardware and software, ensuring a better preoperative planning with a more predictable surgical outcome.

On the basis of the outcome of present surface segmentation studies, companies specialising in CBCT-based surgical planning software and/or CBCT manufacturers may integrate guidelines and protocols for their customers on how to interpret bone quality for a specific CBCT scanning. Dentists could apply this technique on CBCT to get more insight in the local bone structure and thus predict if a potential host bed is of good quality, is healing well and would potentially allow a successful implant placement.

*IPR exploitable measures taken or intended:*
No IPR measures have been taken or are intended.

*Further research necessary, if any:*
The present method for trabecular segmentation might be elaborated to provide data based on larger datasets. This would be research aiming at defining imaging standards for specific applications and equipment.

*Potential / expected impact (quantify where possible):*
The impact can be defined as optimised use of CBCT for specific clinical applications.

**Health Economics Methodology**

*Purpose:*

A methodology for the economic evaluation of the introduction of new diagnostic radiology technologies in oral health care that includes the identification, measurement and valuation of the impacts of technology on the costs to the health care system, patients and their families and society as well as on patient health and well being..

*How the foreground might be exploited, when and by whom:*

National and international professional organisations, health care providers (hospitals, dental Practices) in developing business plans for CBCT services. Academic institutions involved in education and research on diagnostic methods and health economics. The methodology is available now.

*IPR exploitable measures taken or intended:*

None anticipated. The methodology developed in SEDENTEXCT will be published in academic/ professional journals and normal copyright transfer to publishers will be required.

*Further research necessary, if any:*

The methodology is complete, but research to extend the application of the methodology to Randomized Control Studies of the technologies will be facilitated in the future.

*Potential / expected impact (quantify where possible):*

Improved clinical outcomes through more accurate diagnostic information; improved patient well being through more specific service recommendations; improved return on investment in health care resources by Service Providers and increased efficiency in health care resource utilisation.

**Website**

*Purpose:*

The SEDENTEXCT website provides an unbiased, evidence-based source of information about cone beam CT.

*How the foreground might be exploited, when and by whom:*
The website provides background information and training materials on CBCT, suitable for continuous professional development of dentists, dental radiologists and medical physicists, introductory training for undergraduates and postgraduates in these disciplines, and of general interest to researchers, CBCT manufacturers, policy makers and the general public. The SEDENTEXCT website has been available since the early days of the project and will remain available without further update for the foreseeable future.

The website information resources and training materials have been transferred (June 2011) to the European Academy of DentoMaxilloFacial Radiology (EADMFR), assisting in the dissemination amongst dentists of best practice across Europe. The materials appear on the public part of their website, http://www.eadmfr.info and EADMFR will be responsible for future updates to the materials.

*IPR exploitable measures taken or intended:*
The SEDENTEXCT Consortium will formalise the IPR arrangement with EADMFR to provide a licence to use and update the materials, while IPR ownership remains with the Consortium.

*Further research necessary, if any:*
The website requires on-going update to reflect developments in research and changing policies.

*Potential / expected impact (quantify where possible):*
Better education and training of professional staff can be expected to lead to optimised x-ray doses for patients and staff, and better patient outcomes from optimised use of the CBCT devices.