

# “The State of the Art” SEDEXCT Workshop on dental Cone Beam CT

31 March 2011



# What a difference a decade makes....

Eur. Radiol. 8, 1558–1564 (1998) © Springer-Verlag 1998

European  
Radiology

*Original article*

## **A new volumetric CT machine for dental imaging based on the cone-beam technique: preliminary results**

**P. Mozzo<sup>1</sup>, C. Procacci<sup>2</sup>, A. Tacconi<sup>2</sup>, P. Tinazzi Martini<sup>2</sup>, I. A. Bergamo Andreis<sup>2</sup>**

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**Dentomaxillofacial Radiology (1999) 28, 245–248**  
© 1999 Stockton Press All rights reserved 0250–832X/99 \$12.00  
<http://www.stocktonpress.co.uk/dmfr>

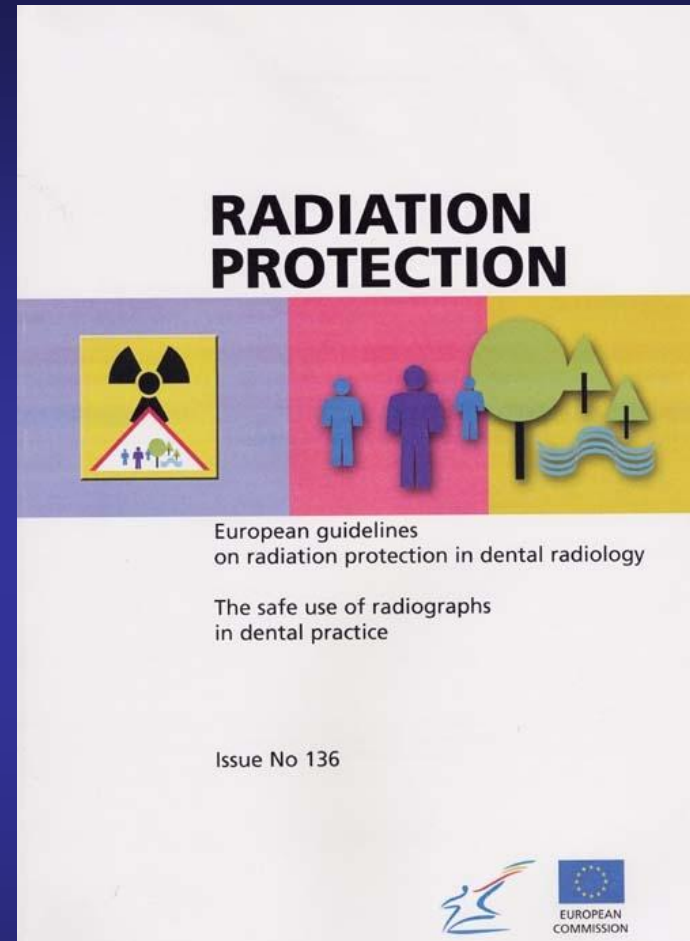
## **Development of a compact computed tomographic apparatus for dental use**

Y Arai<sup>\*1</sup>, E Tammisalo<sup>2</sup>, K Iwai<sup>1</sup>, K Hashimoto<sup>1</sup> and K Shinoda<sup>1</sup>

<sup>1</sup>Department of Radiology, Nihon University School of Dentistry, Tokyo, Japan; <sup>2</sup>Department of Oral Radiology, Institute of Dentistry, University of Turku, Turku, Finland

*(Mozzo et al., 1998; Arai et al., 1999)*

# European Guidelines on Radiation Protection in Dental Radiology (2004)

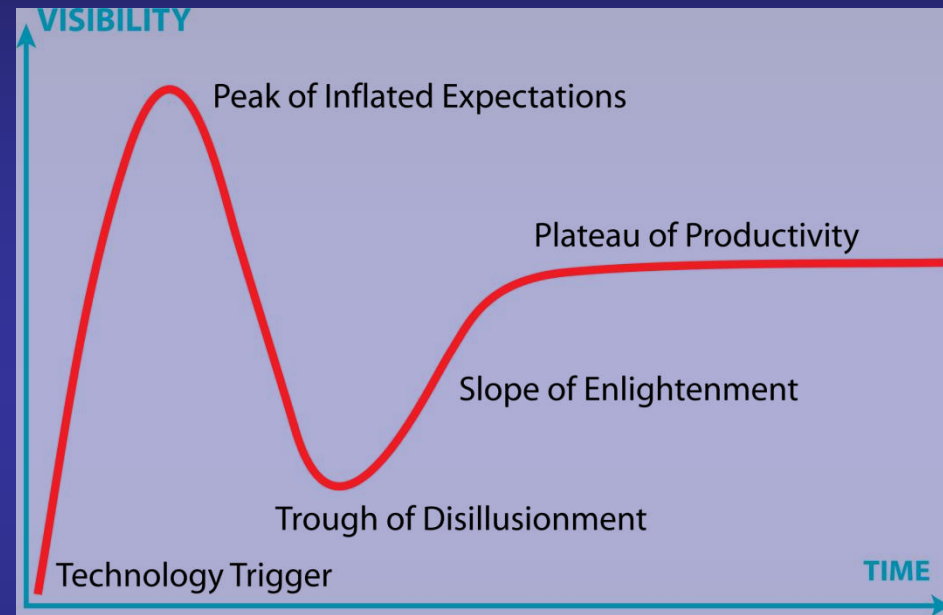


Many CBCT machines  
on the market

Scientific literature  
growing exponentially

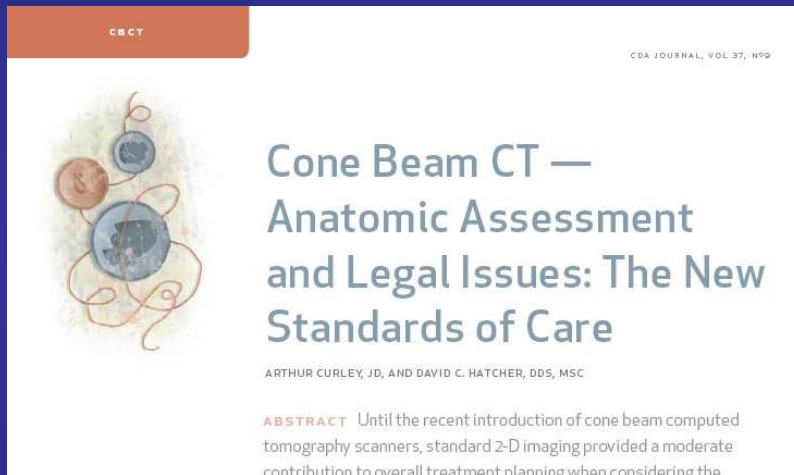
CBCT has revolutionised  
dental and maxillofacial  
radiology

Provoking controversy



Gartner hype cycle

*“In cases of full-mouth orthodontics, the offer of CBCT 3-D imaging has become a standard of care”*



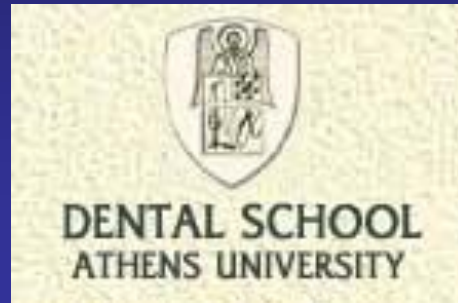
**Curley A, Hatcher DC. J Calif Dent Assoc. 2009 Sep;37(9):653-62**



**New York Times  
22 November 2010**



# European Atomic Energy Community's Seventh Framework Programme FP7/ 2007- 2011



## Aims:

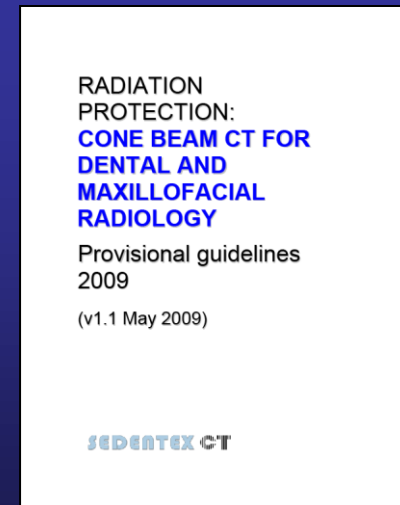
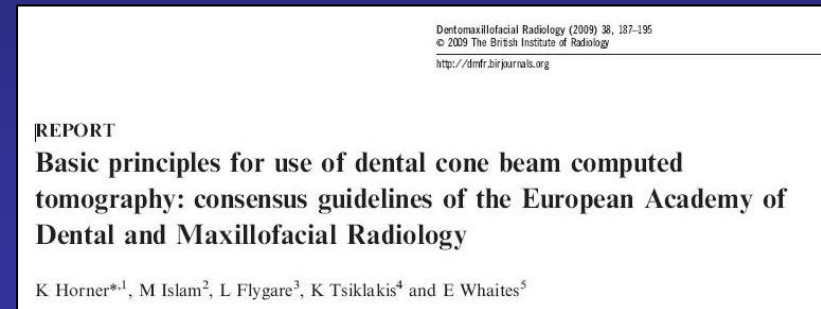
*“The aim of this proposal is the acquisition of key information necessary for sound and scientifically based clinical use of dental Cone Beam Computed Tomography (CBCT). In order that safety and efficacy are assured and enhanced in the ‘real world’, the parallel aim is to use the information to develop evidence-based guidelines dealing with justification, optimisation and referral criteria and to provide a means of dissemination and training for users of CBCT.”*

Six component “Work Packages”

# Work package 1

## *Justification and Guideline development*

To develop evidence-based guidelines on use of CBCT in dentistry, including referral criteria, quality assurance guidelines and optimisation strategies. Guideline development will use systematic review and established methodology, involving stakeholder input.



# Work package 2

## *Dosimetry*

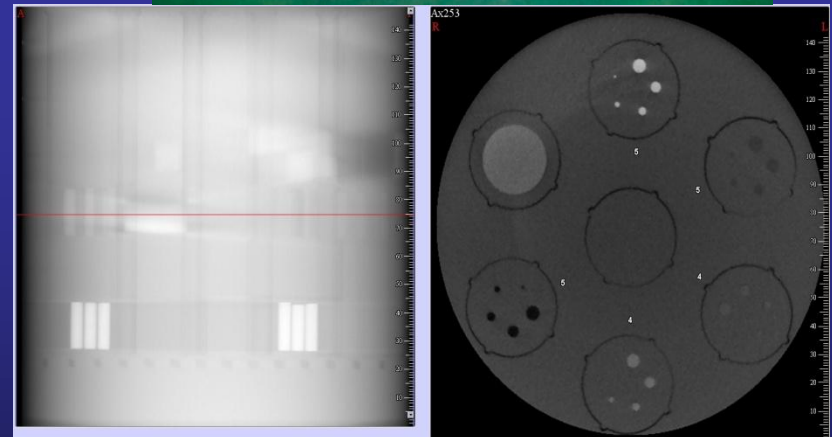
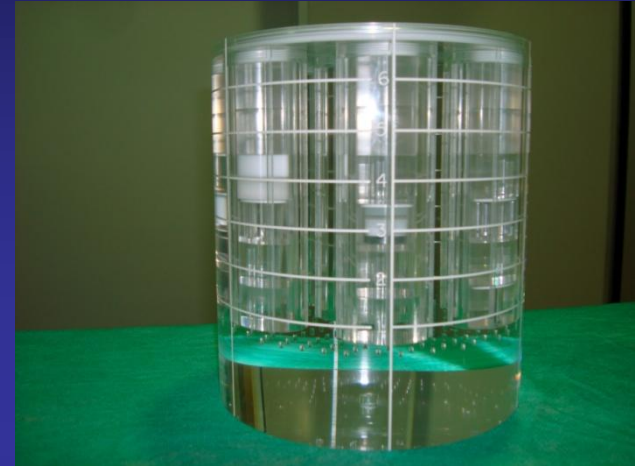
To determine the level of patient dose in dental CBCT, paying special attention to paediatric dosimetry, and personnel dose.



# Work package 3

## *Optimisation*

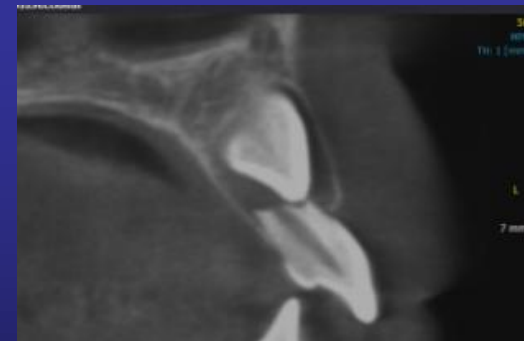
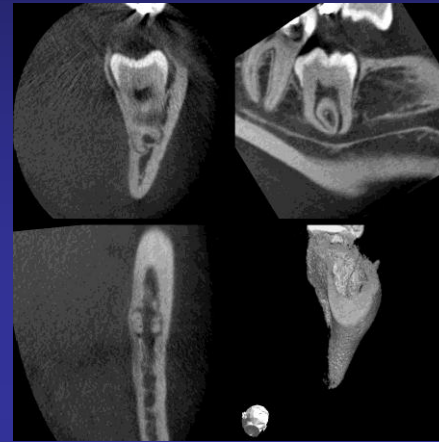
To develop a quality assurance programme, including a tool/tools for quality assurance work (including a marketable quality assurance phantom) and to define exposure protocols for specific clinical applications.



# Work package 4

## *Diagnostic accuracy*

To perform diagnostic accuracy studies for CBCT for key clinical applications in dentistry by use of in vitro and clinical studies.



# Work package 5

## *Cost effectiveness*

To measure cost-effectiveness of important clinical uses of CBCT compared with traditional methods.

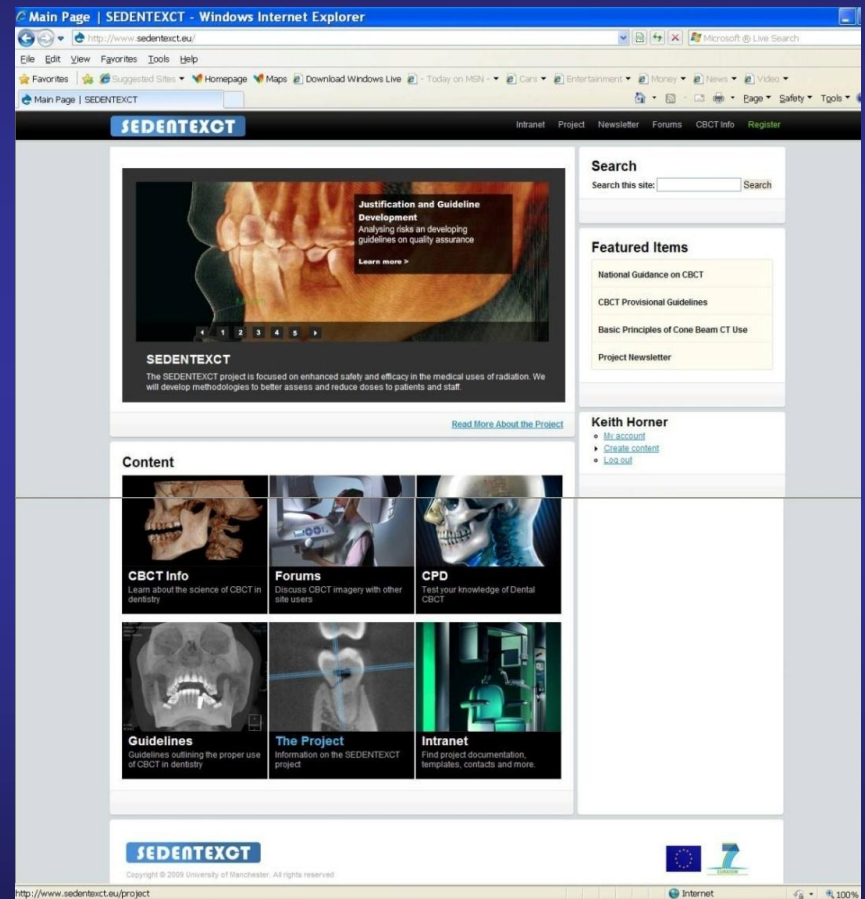


# Work package 6

## Training and valorisation

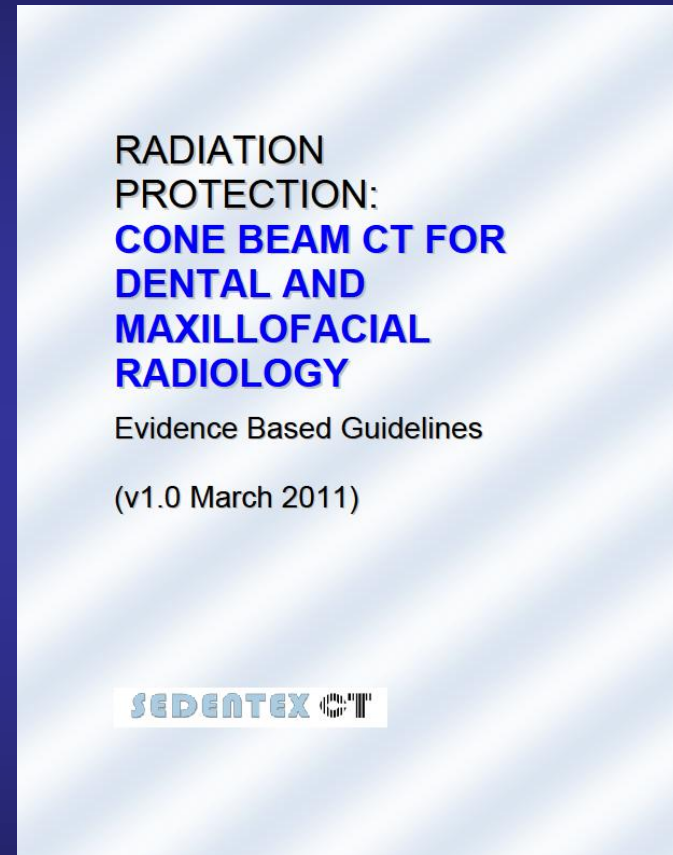
To conduct valorisation\*, including dissemination and training, activities via an 'open access' website.

\*Validation and proof of worth through earnings or a yield



# New Guidelines

v1.0 March 2011



# Guideline methodology

## *Multidisciplinary Guideline development panel*

### *Identification of the literature*

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](http://www.controlled-trials.com))

NICE guidelines ([www.nice.org.uk](http://www.nice.org.uk))

FDI World Dental Federation Guidelines

([www.fdiworldental.org](http://www.fdiworldental.org)).

# Guideline methodology

## *Multidisciplinary Guideline development panel*

### *Identification of the literature*

#### **Box 1. Search strategy developed for MEDLINE (OVID)**

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

# Guideline methodology

## National CBCT documents

### Box 2. National guidelines used as source material

- Advies van de Hoge Gezondheidsraad, 2011.  
[www.hgr-css.be](http://www.hgr-css.be)
- Haute Autorité de Santé., 2009.  
<http://www.has-sante.fr>
- Health Protection Agency, 2010a.
- Health Protection Agency, 2010b.
- Leitlinie der DGZMK., 2009:
- Qualitätssicherungs-Richtlinie – QS-RL, 2004, S. 731-777.
- Schulze D, Schulze R. 2006
- Statens strålevern, 2010.
- Sundhedsstyrelsen, 2009.

# Guideline methodology

## Critical appraisal

## Bias grading

- High risk
- + Moderate risk
- ++ Low risk

## “Justification” studies”

- SIGN
- QUADAS tool for assessment of studies of diagnostic accuracy

## Other studies

- Generic proformas

# Guideline methodology

Grade	
<b>A</b>	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>B</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+
<b>C</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 2++
<b>D</b>	Evidence level 3 or 4; or extrapolated evidence from studies rated as 2+
<b>GP</b>	Good Practice (based on clinical expertise of the guideline group)

# Examples

*CBCT may be indicated for the localised assessment of an impacted tooth (including consideration of resorption of an adjacent tooth) where the current imaging method of choice is conventional dental radiography and when the information cannot be obtained adequately by lower dose conventional (traditional) radiography*

**C**

*All CBCT examinations must be justified on an individual basis by demonstrating that the benefits to the patients outweigh the potential risks. CBCT examinations should potentially add new information to aid the patient's management*

**ED BP**

# New Guidelines

57 recommendations  
or statements

*A grade: 0*

*B grade: 6*

*C grade: 9*

*D grade: 10*

*GP: 24*

*ED/BP: 8*



Consensus process  
by EADMFR and  
EFOMP

# Contents

- 1 Introduction and guideline development
  - 2 Radiation dose and risk
  - 3 Basic Principles
  - 4 Justification and referral criteria
  - 5 Equipment factors in the reduction of radiation risk to patients in CBCT
  - 6 Quality standards and quality assurance
  - 7 Staff protection
  - 8 Economic evaluation
  - 9 Training
- Appendix 1 Screening protocol*
- Appendix 2 Measurement accuracy studies*
- Appendix 3 Evidence tables – justification and referral criteria*
- Appendix 4 Results of STARD*
- Appendix 5 Quality control*
- Appendix 6 Summary of recommendations*
- Appendix 7 Glossary*

## Quality Control for Dental Cone Beam Computed Tomography (CBCT) Systems

### 1 Introduction

A Quality Control Programme 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.

A programme of equipment tests for dental cone beam CT should consider the following aspects:

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

Such a programme is a requirement of the European Union Medical Exposures Directive<sup>1</sup> as part of the optimisation process to ensure patient dose is as low as reasonably practicable whilst achieving clinically adequate image quality. Any practice undertaking medical exposure should have access to the advice of a medical physics expert on such matters. The Medical Exposures Directive is currently under revision<sup>2</sup> and the role of the Medical Physics Expert is given higher prominence in the most recent draft.

Testing and patient dose assessment is carried out when the equipment is first installed as part of the commissioning process and then throughout the life of the equipment<sup>3</sup>. 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.

A range of tests are appropriate for dental CBCT looking at different aspects of the equipment and image display. National guidance exists in some EU countries<sup>4</sup> and the SEDENTEXCT project<sup>5</sup> has developed phantoms to facilitate carrying out a wide range of measurements. 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.

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

# Programme for the day:

<b>10.15</b> Dosimetry of dental CBCT	Ria Bogaerts
<b>10.55</b> Optimisation and quality control	Kostas Tsiklakis
<b>11.35</b> <i>Break</i>	
<b>12.00</b> Diagnostic efficacy	Reinhilde Jacobs
<b>12.40</b> <i>Lunch</i>	
<b>13.40</b> Breakout groups and plenary meeting	
<b>14.20</b> Professional Education in CBCT	Hugh Devlin
<b>14.50</b> Health Economics of CBCT	Christina Lindh
<b>15.20</b> <i>Break</i>	
<b>15.50</b> Justification of CBCT and Guidelines for clinical use	Vivian Rushton
<b>16.30</b> Audience and panel discussion	
<b>16.50</b> Concluding remarks	
<b>17.00</b> <i>Close</i>	

**Acknowledgement:** *The research leading to these results has received funding from the European Atomic Energy Community's Seventh Framework programme FP7/ 2007-2011 under grant agreement no. 212246 (SEDEXCT: Safety and Efficacy of a New and Emerging Dental X-ray Modality).*

