Evaluation and routine testing in medical imaging departments –

Part 3-4: Acceptance tests – Imaging performance of dental X-ray equipment

Essais d'évaluation et de routine dans les services d'imagerie médicale –

Partie 3-4: Essais d'acceptation – Performance d'imagerie des appareils de radiographie dentaire
# CONTENTS

FOREWORD .................................................................................................................................. 4

INTRODUCTION .................................................................................................................... 6

Clause

1 Scope and object ............................................................................................................. 7  
1.1 Scope ..................................................................................................................... 7  
1.2 Object ..................................................................................................................... 7

2 Normative references ....................................................................................................... 8

3 Terminology ..................................................................................................................... 8  
3.1 Degree of requirements ........................................................................................... 8  
3.2 Use of terms ........................................................................................................... 9  
3.3 Defined terms ......................................................................................................... 9

4 General aspects of ACCEPTANCE TESTS ............................................................................. 9  
4.1 General conditions to be considered in test procedures ........................................... 9  
4.2 Documents and data for the tests .......................................................................... 10  
4.3 Test conditions ...................................................................................................... 10  
4.4 Scope of tests ....................................................................................................... 11  
4.5 Test equipment including PHANTOMS and TEST DEVICES .......................................... 11  
4.6 Evaluating the test results ..................................................................................... 13

5 Test methods for dental X-RAY EQUIPMENT with intra-oral X-RAY IMAGE RECEPTOR ............. 13  
5.1 Visual and functional tests ..................................................................................... 13  
5.2 *X-RAY TUBE VOLTAGE ............................................................................................ 13  
5.3 *TOTAL FILTRATION ................................................................................................. 14  
5.4 *FOCAL SPOT of the X-RAY TUBE .............................................................................. 14  
5.5 Limitation and alignment of the X-RAY BEAM ........................................................... 15  
5.6 FOCAL SPOT TO SKIN DISTANCE ................................................................................ 15  
5.7 *Reproducibility of RADIATION OUTPUT ..................................................................... 16  
5.8 LINE PAIR RESOLUTION ............................................................................................ 16  
5.9 LOW CONTRAST RESOLUTION ................................................................................... 16

6 Test methods for dental panoramic X-RAY EQUIPMENT with extra-oral X-RAY IMAGE RECEPTOR ................................................................. 17  
6.1 Visual and functional tests ..................................................................................... 17  
6.2 X-RAY TUBE VOLTAGE .............................................................................................. 17  
6.3 TOTAL FILTRATION ................................................................................................... 17  
6.4 FOCAL SPOT of the X-RAY TUBE ............................................................................... 17  
6.5 Limitation and alignment of the X-RAY BEAM ........................................................... 17  
6.6 FOCAL SPOT TO SKIN DISTANCE ................................................................................ 18  
6.7 Reproducibility of RADIATION OUTPUT ...................................................................... 18  
6.8 LINE PAIR RESOLUTION ............................................................................................ 19  
6.9 LOW CONTRAST RESOLUTION ................................................................................... 19  
6.10 RADIOGRAPHIC FILM cassettes with INTENSIFYING SCREENS ....................................... 19  
6.11 Image homogeneity .................................................................................................. 19  
6.12 Indicators for patients' positioning ......................................................................... 20  
6.13 Panoramic layer ...................................................................................................... 20
7 Test methods for dental cephalometric X-RAY EQUIPMENT with extra-oral X-RAY IMAGE RECEPTOR

7.1 Visual and functional tests

7.2 X-RAY TUBE VOLTAGE

7.3 TOTAL FILTRATION

7.4 FOCAL SPOT of the X-RAY TUBE

7.5 Limitation and alignment of the X-RAY BEAM

7.6 FOCAL SPOT TO SKIN DISTANCE

7.7 Reproducibility of RADIATION OUTPUT

7.8 LINE PAIR RESOLUTION

7.9 LOW CONTRAST RESOLUTION

7.10 RADIOGRAPHIC FILM cassettes with INTENSIFYING SCREENS

8 Test report and statement of compliance

Annex A (normative) Terminology – Index of defined terms

Annex B (informative) Examples of requirements (accuracy, tolerances, discrepancies) according to actual IEC standards or state of the art

Annex C (informative) ACCEPTANCE TEST for processing of non-screen dental X-ray films (non-screen film)

Bibliography

Figure 1 – Dental X-RAY EQUIPMENT with intra-oral X-RAY IMAGE RECEPTOR measuring arrangement for AIR KERMA and resolution

Figure 2 – Dental X-RAY EQUIPMENT with intra-oral X-RAY IMAGE RECEPTOR measuring arrangement for AIR KERMA and resolution

Figure 3 – Dental panoramic X-RAY EQUIPMENT with extra-oral X-RAY IMAGE RECEPTOR measuring arrangement for AIR KERMA and resolution

Figure 4 – Example of a dental panoramic X-RAY EQUIPMENT with extra-oral digital X-RAY IMAGE RECEPTOR measuring arrangement for AIR KERMA, resolution, image homogenity and panoramic layer

Figure 5 – Example of a cephalometric X-RAY EQUIPMENT with extra-oral X-RAY IMAGE RECEPTOR measuring arrangement for AIR KERMA and resolution

Figure 6 – Dental PHANTOM (example)

Figure 7 – Dental PHANTOM for digital image acquisition or processing parts (example)

Table B.1 – Typical values of FOCAL SPOT dimensions for NOMINAL FOCAL SPOT VALUES
FOREWORD

1) The IEC (International Electrotechnical Commission) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of the IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, the IEC publishes International Standards. Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. The IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.

2) The formal decisions or agreements of the IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested National Committees.

3) The documents produced have the form of recommendations for international use and are published in the form of standards, technical specifications, technical reports or guides and they are accepted by the National Committees in that sense.

4) In order to promote international unification, IEC National Committees undertake to apply IEC International Standards transparently to the maximum extent possible in their national and regional standards. Any divergence between the IEC Standard and the corresponding national or regional standard shall be clearly indicated in the latter.

5) The IEC provides no marking procedure to indicate its approval and cannot be rendered responsible for any equipment declared to be in conformity with one of its standards.

6) Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. The IEC shall not be held responsible for identifying any or all such patent rights.

International Standard IEC 61223-3-4 has been prepared by subcommittee 62B: Diagnostic imaging equipment, of IEC technical committee 62: Electrical equipment in medical practice.

The text of this standard is based on the following documents:

<table>
<thead>
<tr>
<th>FDIS</th>
<th>Report on voting</th>
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<tbody>
<tr>
<td>62B/393/FDIS</td>
<td>62B/402/RVD</td>
</tr>
</tbody>
</table>

Full information on the voting for the approval of this standard can be found in the report on voting indicated in the above table.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 3.

Annex A forms an integral part of this standard.

Annexes B and C are for information only.
In this standard, the following print types are used:

- requirements, compliance with which can be tested, and definitions: roman type;
- explanations, advice, notes, general statements, exceptions and references: smaller type;
- **test specifications**: italic type;
- **TERMS DEFINED IN IEC 60601-1, IN IEC 60788, IN IEC 61223-1 OR IN OTHER IEC PUBLICATIONS REFERENCED IN ANNEX A**: SMALL CAPITALS.

The committee has decided that the contents of this publication will remain unchanged until 2005. At this date, the publication will be

- reconfirmed;
- withdrawn;
- replaced by a revised edition, or
- amended.

A bilingual version of this standard may be issued at a later date.
INTRODUCTION

This part of IEC 61223 is part of a series of International Standards which gives methods of acceptance testing and constancy testing for subsystems and systems (for example, diagnostic X-RAY EQUIPMENT) including film processing.

Some provisions or statements in this standard require additional information. Such information is presented in annex B. An asterisk in the left margin of a clause or subclause indicates the presence of such additional information.
1 Scope and object

1.1 Scope

This part of IEC 61223 applies to those components of dental X-RAY EQUIPMENT using radiographic imaging systems which influence the image quality and PATIENT dose.

This standard applies to the performance of the ACCEPTANCE TEST on dental X-RAY EQUIPMENT with intra-oral X-RAY IMAGE RECEPTOR and dental X-RAY EQUIPMENT with extra-oral X-RAY IMAGE RECEPTOR (for example, dental panoramic X-RAY EQUIPMENT or cephalometric X-RAY).

This standard applies to dental film and digital image acquisition and processing.

1.2 Object

This standard defines

a) the essential parameters which describe the performance of the above-mentioned dental X-RAY EQUIPMENT with regard to imaging properties and PATIENT dose;

b) methods of testing and whether measured quantities related to those parameters comply with the specified tolerances.

These methods rely mainly on non-invasive measurements, using appropriate test equipment, performed during or after the installation is completed. Signed statements covering steps in the installation procedure may be used as part of the acceptance testing.

The aim is to verify compliance of the installation with specifications affecting the image quality and PATIENT dose, and to detect malfunctions that are not in agreement with those specifications.

This standard does not in itself specify tolerances for the parameters under investigation. Neither is it intended to consider

c) aspects of mechanical and electrical safety;

d) aspects of mechanical, electrical and software performance, unless they are essential to the performance of the tests directly affecting image quality and PATIENT dose.
2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this part of IEC 61223. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this part of IEC 61223 are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of IEC and ISO maintain registers of currently valid International Standards.

IEC 60336:1993, X-ray tube assemblies for medical diagnosis – Characteristics of focal spots
IEC 60417-1:1998, Graphical symbols for use on equipment – Part 1: Overview and application
IEC 60522:1999, Determination of the permanent filtration of X-ray tube assemblies
IEC 60601-1:1988, Medical electrical equipment – Part 1: General requirements for safety
IEC 60788:1984, Medical radiology – Terminology
IEC 60878:1988, Graphical symbols for electrical equipment in medical practice
IEC 61267:1994, Medical diagnostic X-ray equipment – Radiation conditions for use in the determination of characteristics
ISO 2092:1981, Light metals and their alloys – Code of designation based on chemical symbols