

IEC Standards and Computed Tomography

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Current CT Standards

- Safety (IEC 60601-2-44)
 - Edition 1 (published 1999)
 - Edition 2 (published 2001)
 - Edition 2 Amendment 1 (agreed, published 2002?)
- Acceptance (IEC 61223-3-5)
 - in process (for publication beginning of 2004)
- Constancy Test (IEC 1223-2-6)
 - published in 1994, due for revision
- Image Quality and Dose (all modalities)
 - suspended

IEC and BSI

- UK National Committee is BSI:
 - CH/62/2 Diagnostic Imaging Equipment
 - Covers all aspects of diagnostic radiology
 - “Responsible for UK input into IEC standardization in the field of Diagnostic Imaging Equipment”
- Organisations represented
 - IPEM, CoR, BIR, MDA, NRPB, Health and Safety Executive etc..(..Association of Master Forgers ??)
- BSI Committee members wrt CT:
 - SE (MDA), Paul Shrimpton (NRPB), Fred Wright (Radiologist), Arnold Rust (IPEM, DRSIG)...

IEC and BSI

- Numbering consistent with IEC numbers
 - eg CT Safety Standard: IEC 60601-2-44
BSI EN 60601-2-44
- Some other recent standards
 - Particular requirements for safety.....
 - IEC BS EN 60601 - 2 - 37 : 2001
...of ultrasonic medical diagnostic and monitoring equipment
 - IEC BS EN 60601 - 2 - 33 : Oct 2002 (supercedes 1996)
...of magnetic resonance equipment for medical diagnosis
- web info. @ <http://www.edd.bsi.org.uk>, [bsi.org.uk](http://www.bsi.org.uk), [bsi-global.com](http://www.bsi-global.com)

IEC CT Acceptance Test Working Group

- Manufacturer Representatives
 - Philips (Haifa, Holland, Cleveland)
 - GE (Milwaukee, Japan)
 - Siemens
 - German Industry CT physicists (Siemens and Philips)
 - Toshiba
 - Analogic
 - Hitachi
- National Committee Representatives
 - USA → AAPM, FDA
 - BSI → MDA, NRPB, IPEM
 - other European groups
 - JIRA

Process to Achieving a Standard

- Initial Draft
- CD (Committee Draft)
- CDV (Committee Draft for Voting)
- FDIS (Final Draft Industry Standard)
- IS (Industry Standard)

Process (Acceptance)

- **Initial Draft**

- IEC WG review comments

May 2001



- **1st CD (Committee Draft)**

- document distributed to National Committees
 - via BSI to committee members (MDA, NRPB etc)

- formal comments submitted

- IEC WG review comments

Jan 2002



- **2nd CD (Committee Draft)**

- document distributed
 - via BSI to committee members

- formal comments submitted

- IEC WG review comments

June 2002

CTUG, mailbase



Sept 2002



Feb 2003

Process (Acceptance)

- **CDV (Committee Draft for Voting)**
 - document distribution ← **June 2003**
 - voting from each National Committee
 - any further comments submitted
 - IEC WG resolve comments
- **FDIS (Final Draft Industry Standard)**
 - distribution for public comment
 - voting from each National Committee
- **IS (Industry Standard)**
 - ie IEC xxx, BSI EN xxx
- **'Maintenance' team established**

Submission of Comments

- Comments submitted in required form
 - IEC rules : WG committee must discuss and respond
- Comments submitted in three categories
 - general
 - editorial
 - technical
- Initial Draft and Committee Drafts
 - good cure for insomnia

Submission of Comments

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62B/479/CC

| National Committee | Clause/ Subclause | paragraph Figure/ Table | Type of comment (General/ Technical/ Editorial) | COMMENTS | Proposed change | OBSERVATIONS OF THE WORKING GROUP on each comment submitted |
|--------------------|-------------------|-------------------------|---|---|---|--|
| GB 12 | Page 7 | 1.3 Para.1 | Editorial | Capital letters used for whole paragraph | Use normal type | Problem of Word? |
| Canada 4 | 2 | NOTE | E | superfluous comma before "that" | delete the comma | deleted |
| Canada 5 | 2.104 | NOTE | E | ...imaging processing ... | replace "imaging" by "image" | replaced |
| UK-F2 | 2-106 | | E | Is the equation given in 2-106 the international Hounsfield scale? Is the latter a defined term? | | Agreed by making Hounsfield explicit |
| UK-F1 | | 2.105 | E | What does x mean in the CTDI equation? | | Changed to "x" for multiplication |
| GB 13 | Page 9 | 2.108 | Editorial | Formula uses "x" rather than multiplication symbol | put appropriate symbol in. | Changed to "x" for multiplication |
| GB 14 | | 2.108 | Editorial | Linear attenuation coefficient not defined as μ | add μ to definition (use correct symbol) | Rejected, clear as stated |
| Canada 6 | 2.108 | | E | typo: l | replace l by μ | Problem of the printer? |
| GB 15 | 2.107 | 2nd line | Editorial | Missing capital letter at beginning of sentence | Replace "representation" by "Representation" and add full-stop at end | IEC style-guide: definition to start with small letter |
| GB 16 | 2.109 | 2nd line | Editorial | Should all of this be in capital letters (or only certain words)? | Review format in relation to standard for Document | Problem of Word? |
| GB 17 | | 2.110 | Editorial | Will the source of the references be stayig in or out ? Some refer to IEC 61223-2-6 which is I think just the previous verison of this one (under a different numbering scheme). Or does it refer to another one ? | clarify | Staying in This Std. is 61223-3-6 Definitions are taken from 61223-2-6 "constancy testing" and 60601-2-44 Ed.2 A1 "safety" |
| GB 18 | 2.114 | 2nd line | Editorial | Missing capital letter at beginning of sentence | Replace "relative" by "Relative" | IEC style-guide: |
| Canada 7 | 2.115 | 2 nd line | E | | suggesting to add "coefficient" after "ATTENUATION" | accepted |
| GB 19 | | 2.115 | Editorial | SPACIAL should read SPATIAL | correct spelling | Rejected, clear as given |
| GB 20 | 2.116 | 2nd line | Editorial | Missing capital letter at beginning of sentence | Replace "geometric" with "Geometric" and add full-stop at end | IEC style guide: definition to start with small letter |
| GB 21 | 2.116 | Heading | Editorial | There are two subclauses labelled 2.116 | Change (the second one) to subclause 2.117 | changed |
| GB 22 | (2.117) | 2nd line | Editorial | Missing capital letter at beginning of sentence | Replace "volume" with "Volume" and add full-stop at end | Full-stop added |
| DE 1 | 2.119 | | E | | Include description of uniformity from 60601-2-6 section 5.1.5 | Text in from 60601-2-6 section 5.1.5 does not belong to definition |

Submission of Comments

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62B/479/CC

| National Committee | Clause/Subclause | paragraph Figure/Table | Type of comment (General/Technical/Editorial) | COMMENTS | Proposed change | OBSERVATIONS OF THE WORKING GROUP on each comment submitted |
|--------------------|------------------|------------------------|---|--|---|---|
| GB 68 | | 4.5.4 /Annex FF | Technical | CTDI _w is not defined anywhere. Annex FF is not complete. | Include complete description of CTDI _w | Accepted |
| GB 69 | | 4.5.4 | Technical / Editorial | Not clear where the CTDI ₁₀₀ measurement is to be taken for the collimation or for the kV dependence. (ie is it for just one position in the phantom ? Or is it to be taken for CTDI _w) Its too time consuming to do for CTDI _w Slice collimation ratios can be done in air and just two slices done in body phantom to check consistency (and extreme scatter condition) kV dependence has to be done in phantom. Changes slightly with phantom size. | Clarify position. Suggest centre phantom. | Clarified |
| GB 70 | | 4.5.4 | Editorial / Technical | How many measurements at each position is meant ? One or more to assess repeatability ? We take 3 for CTDI _w for the 10 mm collimation, and then one thereafter. In the phantom we take three per chamber position. Is the document meant to be prescriptive in terms of accuracy of measurement ? | clarify | Clarified, also see 3.3 |
| DE 22 | 4.5.5 | | T | | Add: The CTDI _w shall be within ± 20% of the displayed dose figure | Accepted in principle |
| GB 71 | 4.5.5 | 1st para | Technical | The general term CTDI ₁₀₀ here appears confusing perhaps, without further reference to the location of the measurement. There is no criterion for CTDI _w . | Clarify which data are to be utilised | Clarified |
| GB 72 | 4.6.4 | 1st para | Editorial | L _{for} and L _{back} are incorrect terms (lacking subscript and italics) | Replace with L _{for} and L _{back} , respectively | corrected |
| GB 73 | 4.6.4 | 2nd para | Editorial | C _{for} and C _{back} are incorrect terms (lacking subscript and italics) | Replace with C _{for} and C _{back} | corrected |
| Canada 21 | 4.6.5 | | E | should "should" be replaced by "shall" | | corrected |
| GB 74 | | 4.7 | Technical | Would the result of this test be different if a load was applied to the couch, or if an area outside the iso-centre was being tested. | | Under consideration for the CDV |

Safety Standard IEC 60601-2-44

- Pitch Definitions

- Edition 1 (1999)

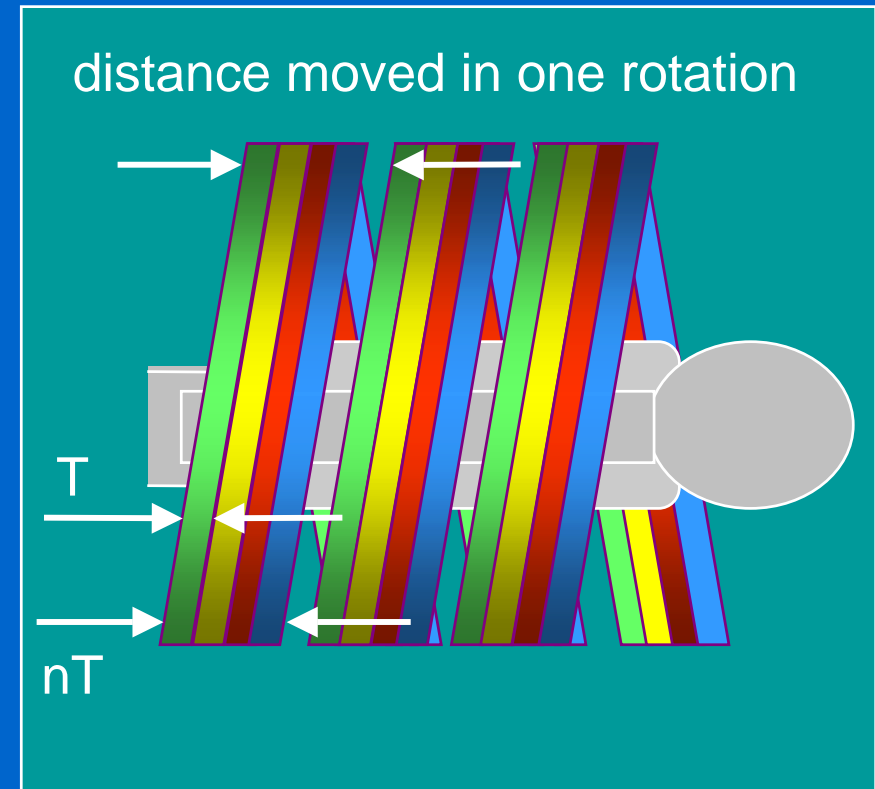
- Pitch = distance / nT
- 'dose pitch' eg $\text{pitch}_x = 1$

- Edition 2 (2001)

- Pitch = distance / T
- 'acquisition pitch' eg $\text{pitch}_z = 4$

- Edition 2 Am. 1 (2002)

- Pitch = distance / nT



T detector group acquisition width
eg 5 mm

nT total detector acquisition width
or nominal beam width eg 4 x 5 mm

Safety Standard IEC 60601-2-44

- CTDI Definitions

- Edition 1

- $CTDI_w$ displayed on console
 - $CTDI_w$ implicitly included correction for pitch
 - EUR Quality Criteria and Reference Dose includes pitch separately when calculating DLP
 - potential for pitch to be included twice

- Edition 2

- As above

- Edition 2, Amendment 1

- $CTDI_{vol}$ defined as the pitch corrected $CTDI_w$
 - $CTDI_w$ represents CTDI averaged in x-y
 - $CTDI_{vol}$ represents CTDI averaged in x-y and z
 - $CTDI_{vol}$ will be the parameter displayed on the console

Acceptance Standard IEC 61223-3-5

- Safety and Acceptance IEC committees
 - combined for consistency
- Acceptance incorporating more multi-slice issues
- Meeting in Sept. 2002
 - Comments: 87 UK, 34 Japan, 28 Germany, 21 Canada
 - scanners in radiotherapy departments ?
 - now addressed
 - CTDI free in air
 - some countries and manuf. wouldn't accept 'CTDI in air' existed
 - a proposed new definition CTFA was rejected
 - measurement of both CTDI in air and $CTDI_w$
 - MTF analysis
 - manufacturers to put MTF software on system for easy access

Contributing to a Standard

- A very effective influence
 - on what the manufacturers specify, test, display etc.
 - eg. MTF analysis software on scanner
 - eg. CTDI displayed on console
 - once a standard is established manufacturers invest in applying it
- Makes a far better standard
 - eventually makes life easier
 - eg. standardised terminology, sensible information
- Comments from experts from many countries and manufacturers
 - educational

Long Term Benefits of a Standard

- Affects the influence a purchaser has with a manufacturer
 - by referring to the standard when problems arise
- Affects the influence a physicist has with a radiology department
 - can be a lever when establishing time for acceptance
 - users become aware of ctdi values
- However
 - creation of a Standard is a long process
 - once established difficult to change until the next revision

Acceptance Standard IEC 61223-3-5

- Next meeting Feb 2002
 - continuation of discussions from September meeting
- Information available
 - September meeting
 - detailed feedback wrt UK comments submitted to the meeting
 - a revised version of the standard
 - existing list of email addresses
 - about 30 people interested, ~ 6 - 8 sets of comments
 - email me
 - if want information or give further comments
 - sue@impactscan.org

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