SIEMENS

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SOMATOM Perspective

System Owner Manual – Dosimetry and imaging performance report

Table of contents

Table of contents

1 Dosimetry and imaging performance report (128-slice and 64-row/64-slice[1])

This chapter provides dose and imaging performance data. The data is in accordance with the US code of federal regulations 21 CFR 1020.33 (c) and the standard of the International Electrotechnical Commission IEC 60601-2-44.

This chapter provides the following information:

- $CTDI_{100}$ for typical CT conditions of operation with regard to typical head, body, cardiac, head perfusion and pediatric body modes
- Dose factors showing the relative changes of $CTDI_{100}$ compared to the $CTDI_{100}$ of each typical mode in varying a scan parameter
- Dosimetry data, such as beam quality, dose profiles, and stray radiation tables
- Image noise and High-Contrast-Resolution (HCR) of the typical modes
- Homogeneity of CT values and low-contrast resolution
- Reconstructable slice thicknesses

1.1 Dose information

1.1.1 General information about dose indication

The CT system provides information about the $CTDI_{vol}$ and Dose Length Product (DLP) as defined by the IEC 60601-2-44 standard. Both values are displayed on the user interface of the scanner before and after each scan range. In addition, these values are stored in the Patient Protocol and the DICOM Structured Dose Report. The $CTDI_{vol}$ represents the average energy dose (expressed as Air KERMA) within a cylindrical PMMA phantom and is aligned with the scanner axis and centered in the scan plane. The phantom diameter to which the displayed $CTDI_{vol}$ refers depends on the default application of the used protocol.

In general, the values of the body region “Body” are also used for the body region “Neck” .

Child protocols are recommended for pediatric patients under the age of 12 years and with a normal body size. For child protocols, factors for conversion of the displayed $CTDI_{vol}$ and DLP for the 32 cm phantom to equivalent $CTDI_{vol}$ and DLP for the 16 cm phantom are stated.

The CTDI values given in this manual are valid for deactivated CARE Dose 4D , as the feature is not adapted to phantom measurements.

Further information regarding dose reduction functions is provided in the *syngo CT Instructions for use*.

1) 64-row/64-slice is only for China and Japan

1.1.2 Phantoms and methods

According to:

21 CFR 1020.33 (c)(3)(v)

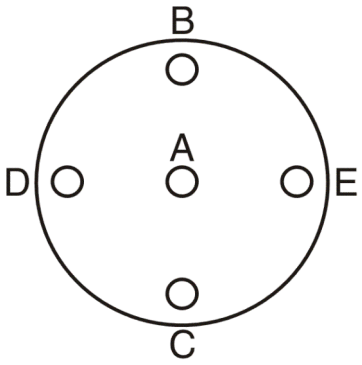
IEC 60601-2-44 (Ed. 3.1) 203.108

This chapter describes both phantoms and methods used to establish the dose values reported below. It also describes how to measure and determine $CTDI_{vol}$, in order to verify against the value displayed at the scanner.

The phantoms used to measure the CTDI values are circular cylinders of PMMA of diameter 16 cm (for head applications) or 32 cm (for body applications), and with a length of at least 14 cm. They contain holes parallel to the axis of the phantom (A – E) to hold 100 mm dose chambers.

Phantoms are aligned with the scanner axis and centered in the scan field. A dose chamber with an active length of 100 mm has been used for the dose measurements. All dose values are given in Air KERMA.

$CTDI_{100}$ is measured in the center (A) and peripheral drillings at 3 o'clock, 6 o'clock, 9 o'clock and 12 o'clock positions (B – E).



$CTDI_{100}$ locations in dosimetry phantoms with the line of sight towards the front side of the gantry

To ensure correct dose measurements, it is recommended to use a dosimeter conforming to IEC 61674. The dosimeter needs to be calibrated with beam qualities suitable for the CT energy spectrum examined, for example, CT beam qualities "RQT" according to IEC 61267.

The dose is measured in single axial scans, which enables the dose chamber to measure the integrated dose profile along the z-direction over 10 cm, centered to the scan plane. The magnitude of the measured values should lay above the accuracy of the dosimeter. Therefore, it may be necessary to select a reasonably large tube current and exposure time or to average the dosimeter readings over several scans. For measurements with the dose chamber in one of the peripheral positions of the phantom, averaging over several scans is highly recommended, otherwise the measured values may be distorted by the position of the scan start angle.

IEC 61674: 2012

'Medical electrical equipment – Dosimeters with ionization chambers and/or semiconductor detectors as used in X-ray diagnostic imaging'

IEC 61267: 2005

'Radiation conditions for use in the determination of characteristics'

To calculate the $CTDI_{100}$ from the dosimeter readings (usually displayed as dose integrated over z-direction, i.e., as Length-Dose-Product (DLP), for example in mGy·cm³) the value has to be divided by the nominal beam collimation. The nominal beam collimation is equal to the acquisition displayed at the scanner's console (for example. Acquisition 32 × 0.6 mm = 1.92 cm).

$$CTDI_{100} = \frac{1}{N \times T} \cdot \int_{-50\,mm}^{+50\,mm} D(z)\ dz = \frac{LDP}{NxT}$$

LDP – measured Length-Dose-Product [mGy·cm]

Note that the reading may also be displayed as dose averaged over the chamber length, e.g. in mGy.

NxT – Nominal Beam Collimation [cm]

This is valid for all nominal beam collimations ≤ 4 cm.

The $CTDI_w$ is the sum of a third of the $CTDI_{100}$ measured in the phantom's central chamber position ($CTDI_{100}^c$) and two thirds of the average of $CTDI_{100}$ measured in the phantom's four peripheral chamber position ($CTDI_{100}^p$).

$$CTDI_w = {}^1/_3 \cdot CTDI_{100}^c + {}^2/_3 \cdot \overline{CTDI_{100}^p}$$

According to it's definition, $CTDI_w$ needs to be derived from $CTDI_{100}$ measured in single axial scans. In this situation the $CTDI_{vol}$ is equal to the $CTDI_w$.

In general, the $CTDI_{vol}$ displayed is derived from the $CTDI_w$ by multiplication with a factor that takes into account the table feed during scanning:

For spiral scanning	$CTDI_{vol} = \frac{CTDI_w}{p}$
For axial scanning	$CTDI_{vol} = CTDI_w \cdot \frac{NxT}{v_f}$
For axial scanning without table feed	$CTDI_{vol} = n \cdot CTDI_w$
CT_p – Pitch factor **NxT – Nominal collimation** **v_f – Table feed per scan**	

1.1.3 Typical CT conditions of operation

According to:

21 CFR 1020.33 (c)(1)

IEC 60601-2-44: 2002, 29.1.102.1

IEC 60601-2-44: 2012, 203.109.1

The following table provides scan parameter settings for typical modes of operation according to the default setting of the Siemens scan protocols (with deactivated CARE Dose 4D).

Typical CT conditions of operation:

Application type	Typical Head	Typical Body	Typical Cardiac	Typical Head Perfusion	Typical Pediatric Body
Patient type	Adult	Adult	Adult	Adult	Child
Scan type	Sequence	Spiral	Sequence	Multiscan	Spiral
Protocol name	HeadSeq	Abdomen Routine	CaScore	NeuroPCT	Abdomen Routine
Tube voltage	130 kV	130 kV	130 kV	80 kV	110 kV
Tube current time product	200 mAs	120 eff. mAs	30 mAs/rot	150 mAs	98 eff. mAs
Tube current	100 mA	120 mA	74 mA	150 mA	229 mA
Rotation time	1 s	0.6 s	0.48 s	1 s	0.6 s
Number of scans	8	1	4	1	1
Scan time	2 s	6.4 s	0.4 s	40 s	3.4 s
Scan length	132.7 mm	200 mm	135.1 mm	0 mm	200 mm
Pitch factor or table feed	17.2 mm	0.6	34.5 mm	0	1.4
Collimation	32 × 0.6 mm	64 × 0.6 mm	64 x 0.6 mm	32 × 1.2 mm	64 × 0.6 mm
Data acquisition	32 × 0.6 mm	64 × 0.6 mm	64 × 0.6 mm	32 × 1.2 mm	64 × 0.6 mm
Total collimation	19.2 mm	38.4 mm	38.4 mm	38.4 mm	38.4 mm
Reconstructed slice width	5 mm	5 mm	3 mm	10 mm	5 mm
Kernel	H31s	B41s	B35s	H31s	B41s

1.1.4 $CTDI_{100}$ value for typical CT conditions of operation

According to:

21 CFR 1020.33 (c)(2)(i)

IEC 60601-2-44: 2002, 29.1.102.1(a)

IEC 60601-2-44: 2012, 203.109.1(a)

The following table indicates the CTDI values for typical modes specified in (➔ Page 8 *Phantoms and methods*)

There is no significant difference in the exposure of the peripheral chamber positions. The stated dose chamber positions are B - E according to their positions in the phantom (up, down, left, and right). See (➔ Page 8 *Phantoms and methods*)

$CTDI_{100}$ values of the typical CT conditions of operation:

Application type	Typical Head	Typical Body	Typical Cardiac	Typical Head Perfusion	Typical Body
Patient size	Adult	Adult	Adult	Adult	Child
CTDI phantom	Ø 16 cm	Ø 32 cm	Ø 32 cm	Ø 16 cm	Ø 32 cm
$CTDI_{100}$ [mGy]	per scan	per rotation	per scan	per scan	per rotation

Application type	Typical Head	Typical Body	Typical Cardiac	Typical Head Perfusion	Typical Body
Patient size	Adult	Adult	Adult	Adult	Child
Chamber position A (central) [mGy]	48.3	5.0	2.1	367.6	6.2
Chamber position B (Up) [mGy]	50.7	9.4	3.9	410.3	12.2
Chamber position C (down) [mGy]	50.8	9.4	3.9	410.3	11.9
Chamber position D (left) [mGy]	50.2	9.4	3.9	402.8	12.0
Chamber position E (right) [mGy]	49.4	9.4	3.9	394.1	12.2
Average peripheral [mGy]	50.3	9.4	3.9	404.4	12.1
$CTDI_w$ [mGy]	49.6	7.9	3.3	392.1	10.1
$CTDI_{vol}$ [mGy]	55.4	13.2	3.7	392.1	7.2

1.1.5 Dose factors related to the $CTDI_{100}$ for typical CT conditions of operation

According to:

21 CFR 1020.33 (c)(2)(ii)

21 CFR 1020.33 (c)(2)(iii)

IEC 60601-2-44: 2002, 29.1.102.1(b), (c)

IEC 60601-2-44: 2012, 203.109.1(b), (c)

The system provides one permanent shaped X-ray beam filter as default settings for all applications, so the $CTDI_{100}$ is influenced by the following selectable scan parameters:

- kV
- Acquisition
- mAs values (mAs, eff. mAs, mAs/rot)

The $CTDI_{100}$ is not influenced by the rotation time or recon parameters, such as Kernel or FoV.

In the following tables, the $CTDI_{100}$ for the typical mode is represented by the value 1.00, shown in bold. $CTDI_{100}$ for varying scan parameters are given as a proportion of the $CTDI_{100}$ for the typical mode.

Dose factors related to the $CTDI_{100}$ for varying tube voltage:

Tube voltage		Typical Head	Typical Body	Typical Cardiac	Typical Head Perfusion	Typical Pediatric Body
		CTDI Phantom Ø 16 cm	CTDI Phantom Ø 32 cm	CTDI Phantom Ø 32 cm	CTDI Phantom Ø 16 cm	CTDI Phantom Ø 32cm
80 kV	Central	0.27	0.22	0.22	**1.00**	0.34
	Peripheral	0.29	0.26	0.26	**1.00**	0.39
	Weighted	0.28	0.26	0.26	**1.00**	0.38
110 kV	Central	0.69	0.65	0.65	2.53	**1.00**
	Peripheral	0.70	0.68	0.68	2.43	**1.00**
	Weighted	0.69	0.67	0.67	2.46	**1.00**
130 kV	Central	**1.00**	**1.00**	**1.00**	3.66	1.54
	Peripheral	**1.00**	**1.00**	**1.00**	3.48	1.48
	Weighted	**1.00**	**1.00**	**1.00**	3.54	1.49

Dose factors related to the $CTDI_{100}$ for varying acquisition type:

Acquisition	Typical Head	Typical Body	Typical Cardiac	Typical Head Perfusion	Typical Pediatric Body
2 × 1 mm	1.61	1.73	1.73	1.75	1.70
4 × 0.6 mm	1.34	1.44	1.44	1.46	1.42
12 × 0.6 mm	1.21	1.30	1.30	1.30	1.31
2 × 5 mm	0.87	0.94	0.94	0.94	0.94
32 × 0.6 mm	**1.00**	1.08	1.08	1.08	1.08
64 × 0.6 mm	0.93	**1.00**	**1.00**	1.00	**1.00**
32 × 1.2 mm	0.93	1.00	1.00	**1.00**	1.00

Dose factors related to the $CTDI_{100}$ for varying mAs:

Dose factors are valid for deactivated CARE Dose4D.

Current	Typical Head		Typical Body		Typical Cardiac		Typical Head Perfusion		Typical Pediatric Body	
	mAs	factor	eff. mAs	factor	mAs	factor	mAs/rot	factor	eff. mAs	factor
25 mA	50	0.25	25	0.21	10	0.34	25	0.17	11	0.11
74 mA	148	0.74	74	0.61	30	**1.00**	74	0.49	32	0.32
100 mA	200	**1.00**	100	0.83	41	1.36	100	0.67	43	0.44
120 mA	240	1.20	120	**1.00**	49	1.63	120	0.80	51	0.52
150 mA	300	1.50	150	1.25	61	2.03	150	**1.00**	64	0.66
229 mA	457	2.29	229	1.91	93	3.10	229	1.52	98	**1.00**
345 mA	690	3.45	345	2.88	140	4.68	345	2.30	148	1.51

1.1.6 Dose levels causing deterministic radiation effects

According to:

IEC 60601-1-3: 2008, 5.2.4.5+Annex A.2

IEC 60601-2-44: 2012, 203.5.2.4.5,

Certain modes of operation allow selections of scan parameters that may lead to an accumulated peripheral $CTDI_{100}$ of more than 1 Gy. This dose may exceed the threshold for deterministic radiation effects on the patient's skin or eye lenses (see IEC 60601-1-3:2008, Annex A.2, 5.2.4.5).

The accumulated peripheral $CTDI_{100}$ may serve as a rough estimation of skin or eye lens dose. However other factors may influence the dose to cause deterministic radiation effects, for example:

- A deviation of the patient's body diameter from the standard CTDI phantom size may lead to a patient's skin dose that is noticeably higher than indicated by the accumulated peripheral $CTDI_{100}$. Such a deviation may occur, for example, if a body perfusion examination is performed with a very thin patient.
- Using the scan protocol dedicate to body scans to perform head scan (for which the dose estimation should be based on Φ16 cm), may lead to a patient skin dose that is great higher than common estimation.
- Repeating examinations within a short time period (compared to the biological recovery time for deterministic radiation effects) may lead to deterministic radiation damages, even if the accumulated peripheral $CTDI_{100}$ of the single examinations was below 1 Gy.

In general, the accumulated peripheral $CTDI_{100}$ can be derived from the displayed $CTDI_{vol}$ by multiplying the $CTDI_{vol}$ with a given factor that depends on tube voltage.

Ratio of peripheral $CTDI_{100}$ to displayed $CTDI_{vol}$:

Tube voltage	Typical Head Ø 16 cm	Typical Body Ø 32 cm
80 kV	1.0	1.2
110 kV	1.0	1.2
130 kV	1.0	1.2

By using the default Siemens scan protocols for patients with a standard patient size, without changing the default settings of the scan parameters, and without repeating the scans, the accumulated peripheral $CTDI_{100}$ will be kept reasonably below 1 Gy.

The following list gives examples of situations that may lead to an accumulated peripheral $CTDI_{100}$ of 1.0 Gy and above (numbers are approximations). The list refers to default Siemens scan protocols and concentrates on scan modes with relatively high radiation exposure. This list is not exhaustive.

- Use of perfusion protocols with changes in kV, scan times, or mAs, for example:
  - *Neuro PCT* with tube voltage changed from 80 kV to 130 kV (≈ 1.4 Gy)
  - *Neuro PCT* with scan time increased from 40 s to ≈ 100 s
  - *Neuro PCT* with mAs increased from 150 mAs to ≈ 371 mAs
- Scanning of sequence protocols without table feed, for example:
  - Approximately 20 scans of *Head Neuro Seq* without table feed
- Repeating standard sequences or spiral scans within an examination, for example:
  - Repeating application of the default protocol *Head Neuro Seq* (approximately 20 times)
  - Repeating application of the default protocol *Abdomen Routine* (approximately 64 times)
- Use of CARE Vision protocol (without Hand CARE) for Head intervention*
  - By applying 130 kV/130 mA for scan time ≈ 24 s
  - Make 15 s scan with 130 kV by applying mAs ≈ 207 mAs

*) The case may happen according to above hint.

To prevent unintended, excessive exposure, the CT system provides tools for Dose Notification and Dose Alert. The default threshold value for Dose Alert is an accumulated $CTDI_{vol}$ of 1.0 Gy.**

**) In case of applying body scan protocols for thin patients, small children or head examinations, the actual exposure dose may be underestimated. Special calculation need to be applied to prevent excessive exposure even the displayed accumulated $CTDI_{vol}$ is still below 1.0 Gy threshold.

1.1.7 Overview of $CTDI_{100}$ values (mGy/100mAs)

Phantom: Ø 16 cm Application: Routine head								
Voltage	Collimation [mm]	2 x 1	4 x 0.6	12 x 0.6	2 x 5	32 x 0.6	64 x 0.6	32 x 1.2
	Total [mm]	2.0	2.4	7.2	10.0	19.2	38.4	38.4
80 KV	$CTDI_{100}$, central	10.66	8.88	7.95	5.72	6.60	6.10	6.10
	$CTDI_{100}$, peripheral	11.75	9.80	8.74	6.29	7.24	6.71	6.71
	CTDIw	11.39	9.49	8.48	6.10	7.02	6.51	6.51
110 KV	$CTDI_{100}$, central	26.18	21.81	20.06	14.44	16.65	15.42	15.42
	$CTDI_{100}$, peripheral	27.70	23.08	21.19	15.26	17.55	16.31	16.31
	CTDIw	27.19	22.66	20.81	14.99	17.25	16.01	16.01
130 KV	$CTDI_{100}$, central	38.89	32.41	29.06	20.92	24.17	22.30	22.30
	$CTDI_{100}$, peripheral	40.58	33.81	30.39	21.88	25.15	23.39	23.39
	CTDIw	40.01	33.35	29.95	21.56	24.82	23.02	23.02

Phantom: Ø 32 cm Application: Adult body, Pediatric body*								
Voltage	Collimation [mm]	2 x 1	4 x 0.6	12 x 0.6	2 x 5	32 x 0.6	64 x 0.6	32 x 1.2
	Total [mm]	2.0	2.4	7.2	10.0	19.2	38.4	38.4
80 KV	$CTDI_{100}$, central	2.67	2.22	1.98	1.43	1.64	1.51	1.51
	$CTDI_{100}$, peripheral	5.96	4.97	4.49	3.24	3.68	3.45	3.45
	CTDIw	4.87	4.05	3.66	2.63	3.00	2.80	2.80
110 KV	$CTDI_{100}$, central	7.67	6.39	5.87	4.23	4.85	4.49	4.49
	$CTDI_{100}$, peripheral	14.98	12.49	11.54	8.31	9.53	8.82	8.82
	CTDIw	12.55	10.45	9.65	6.95	7.97	7.38	7.38
130 KV	$CTDI_{100}$, central	12.07	10.06	9.06	6.52	7.49	6.93	6.93
	$CTDI_{100}$, peripheral	22.52	18.76	17.00	12.24	14.01	13.03	13.03
	CTDIw	19.03	15.86	14.35	10.33	11.83	11.00	11.00

*) See (→ Page 15 *Conversion factor for $CTDI_{vol}$ for pediatric protocols from Ø 32 cm phantom to Ø 16 cm phantom*) for necessary conversion for pediatric body if necessary

No phantom Free air								
Voltage	Collimation [mm]	2 x 1	4 x 0.6	12 x 0.6	2 x 5	32 x 0.6	64 x 0.6	32 x 1.2
	Total [mm]	2.0	2.4	7.2	10.0	19.2	38.4	38.4
80 KV		19.30	16.08	14.32	10.31	11.85	11.04	11.04
110 KV		40.62	33.97	31.15	22.43	25.83	24.18	24.18
130		57.85	48.21	43.29	31.17	35.98	33.57	33.57

1.1.8 Tolerances for CTDI

According to:

21 CFR 1020.33

IEC 60601-2-44: 2002, 29.1.102.1(d)

IEC 60601-2-44: 2002, 50.101

IEC 60601-2-44: 2012, 203.109.1(d)

IEC 60601-2-44: 2012, 201.12.1.101

IEC 60601-2-44: 2012, Amd.1 203.112

The actual exposure values, such as $CTDI_{100}$, $CTDI_{w}$, $CTDI_{vol}$ and DLP, may deviate from the values displayed at the scanner and from the values stated in this manual.

Tolerances for CTDI values:

	Typical deviation	Max. tolerance
80 kV	within ± 15%	± 40%
110 kV, 130 kV	within ± 15%	± 30%

The linearity of the radiation output (linearity of measured dose related to displayed mAs) is ± 10%.

1.1.9 Conversion factor for $CTDI_{vol}$ for pediatric protocols from Ø 32 cm phantom to Ø 16 cm phantom

The displayed and reported $CTDI_{vol}$ and DLP refers to cylindrical PMMA phantoms of a diameter of 16 cm for head application and of a diameter of 32 cm for body applications (adult and pediatric protocols), according to IEC 60601-2-44.

Since a child's body diameter may typically be better represented by a 16 cm phantom than by a 32 cm phantom, factors for the conversion of $CTDI_{vol}$ and DLP from a phantom size of 32 cm to a phantom size of 16 cm are given in the following table.

Conversion factor for $CTDI_{vol}$:

kV setting	Conversion factor from Ø 32 cm to Ø 16 cm
80 kV	2.3
110 kV	2.2
130 kV	2.1

For a typical pediatric body protocol at 110 kV, the displayed $CTDI_{vol}$ and DLP (related to the Ø 32 cm CTDI-phantom) are 7.23 mGy and 198.82 mGy × cm. For the same protocol, the $CTDI_{vol}$ and DLP of a Ø 16 cm CTDI-phantom are 2.2 times higher than the values of a Ø 32 cm CTDI-phantom, resulting in $CTDI_{vol}$ as 15.69 mGy and DLP as 431.68 mGy × cm.

1.1.10 $CTDI_{vol}$ for topograms

The $CTDI_{vol}$vol for topogram scans may be estimated according to IEC 60601-2-44, Annex B.

Since the collimation (4 × 0.6 mm) and table speed (100 mm/s) for the topogram is fixed, the $CTDI_{vol}$ for topograms is stated in the following table depending on the kV and mA values.

$CTDI_{vol}$ for topograms:

Protocol type	Head	Body
Phantom size	Ø 16 cm	Ø 32 cm
	$CTDI_{vol}$ µGy/mA	$CTDI_{vol}$ µGy/mA
80 kV	2.3	1.0
110 kV	5.4	2.5
130 kV	8.0	3.8

1.1.11 $CTDI_{free\ air}$

According to:

IEC 60601-2-44: 2012, 203.109.2

The $CTDI_{free\ air}$ is stated in the following table based on the typical body mode (shown in bold type) for varying collimation, and kV. Additionally, the $CTDI_{free\ air}$ for the typical head mode is stated.

$CTDI_{free\ air}$ for setting of typical body (bold type) with variation of collimation and kV:

Collimation [mm]	Variation of the collimation						
	2 × 1	4 × 0.6	12 × 0.6	2 × 5	32 × 0.6	64 × 0.6	32 × 1.2
Total [mm]	2.0	2.4	7.2	10.0	19.2	38.4	38.4
80 kV	23.16 mGy	19.30 mGy	17.18 mGy	12.37 mGy	14.23 mGy	13.25 mGy	13.25 mGy
110 kV	48.74mGy	40.77 mGy	37.38 mGy	26.92 mGy	31.00 mGy	29.01 mGy	29.01 mGy
130 kV	69.42 mGy	57.85 mGy	51.95 mGy	37.40 mGy	43.17mGy	**40.29 mGy**	40.29 mGy

$CTDI_{free\ air}$ for setting of Typical Head:

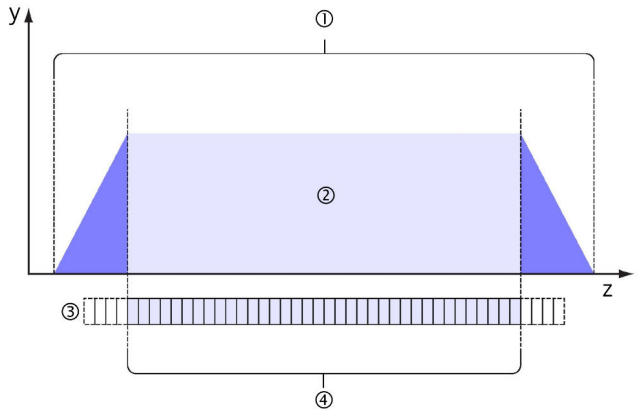
Collimation[mm]	32 × 0.6
Total [mm]	19.2
130 kV	**71.96 mGy**

1.1.12 Geometric efficiency in the z-direction

According to

IEC 60601-2-4: 2012 203.113

The dose efficiency is defined by IEC 60601-2-44 as the integral of the “free in air” in the isocenter along the z-axis over the acquisition range in the z-direction, expressed as percentage of the total integral of the dose profile in the z-direction. The acquisition range is the distance spanned by the selected detector elements along the z-axis. The displayed $CTDI_{vol}$ and DLP reflect the dose efficiency of a collimation according to the definition of $CTDI_{vol}$.



Correlation of dose profile and collimation regarding dose efficiency

y Dose

z z-axis

(1) Total dose profile width

(2) Dose profile

(3) Detector

(4) Acquisition range

Dose efficiencies for the various collimations:

Acquisition	Total collimation	Dose efficiency
64 × 0.6 mm	38.4 mm	91.5%
32 × 1.2 mm	38.4 mm	91.5%
32 × 0.6 mm	19.2 mm	85.8%
12 × 0.6 mm	7.2 mm	71.1%
2 × 5 mm	10.0 mm	96.8%
1 × 10 mm	10.0 mm	96.8%
4 × 0.6 mm	2.4mm	**64.1%**
2 × 1 mm	2.0 mm	**64.1%**
1 × 2 mm	2.0mm	**64.1%**

For CT scans with a dose efficiency lower than 70%, a message containing information about the dose efficiency is displayed after the loading of a scan range. The user has to confirm the message before starting the scan.

1.1.13 Dose profiles

According to:

21 CFR 1020.33 (c)(2)(iv)

21 CFR 1020.33 (c)(3)(iv)

21 CFR 1020.33 (c)(3)(v)

IEC 60601-2-44: 2012 29.1.103.1

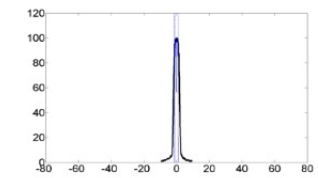
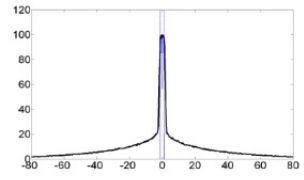
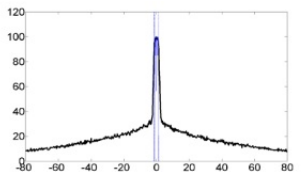
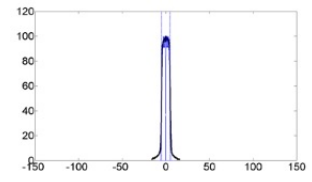
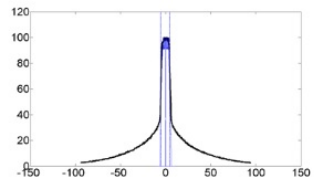
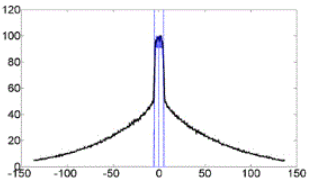
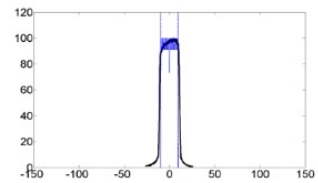
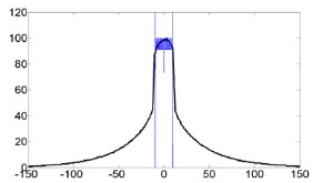
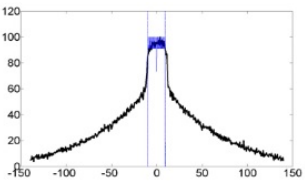
IEC 60601-2-44: 2012 203.110

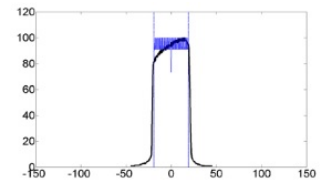
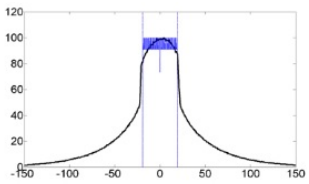
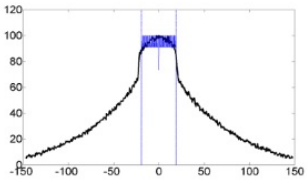
Dose profiles for single axial scans have been measured for the narrowest, a midrange and the widest collimation. For each of these collimations, the dose profiles have been measured in the center of the Ø 16 cm CTDI phantom (head) and in the center of the Ø 32 cm CTDI phantom (body).

The phantoms were centered in the isocenter and aligned with the scanner axes. For the measurements, a semiconductor diode sensor has been moved through the phantom. Each profile is represented as percentage of the maximum value.

In the diagrams below dose profiles (thick lines) are presented as a percentage of their maximum value. Sensitivity profiles for the detector slices used in these collimations are plotted as thin lines. The dotted lines indicate the nominal collimation.

Dose profiles:

	no phantom	phantom 16 cm	phantom 32 cm
4 × 0.6 mm			
2 × 5 mm			
32 × 0.6 mm			

	no phantom	phantom 16 cm	phantom 32 cm
64 × 0.6 mm			
x-Axis: z-position [mm] y-Axis: rel. dose & ssp[%]			

Full Width at Half Maximum (FWHM) of dose profiles:

Collimation	No phantom	Ø 16 cm phantom	Ø 32 cm phantom	Tolerance*
4 × 0.6 mm	3.80 mm	4.01 mm	4.41 mm	± 1.5 mm
2 × 5 mm	10.14 mm	11.10 mm	12.51 mm	± 4.0 mm
32 × 0.6 mm	22.42 mm	24.19 mm	45.97 mm	± 4.0 mm
64 × 0.6 mm	41.97 mm	44.39 mm	79.02 mm	± 4.0 mm
*) The stated tolerances are determined by the accuracy of the measurement method.				

For acceptance testing dose profile widths are measured using film (GAFCHROMIC XR-QA) and without any phantom. The tube is fixed and positioned at 12 o'clock. The exposure parameters are chosen to overexpose the film (130 kV, 160 mA, 6 s, twice). Using this method no densitometry is needed to evaluate the film. The width of the blackened range is a measure for the base width of the profile. Nominal values and tolerances are defined.

Dose profile widths measured using film:

Collimation	Nominal blackening width	Tolerance
4 × 0.6 mm	5.2 mm	± 1.0 mm
2 × 5 mm	12.4 mm	± 1.5 mm
32 × 0.6 mm	24.7 mm	± 2.0 mm
64 × 0.6 mm	44.2 mm	± 2.0 mm

1.1.14 Beam quality, leakage technique factors and minimum filtration

According to:

21 CFR 1020.30 (h)(2)(i)

21 CFR 1020.30 (h)(4)(ii)

21 CFR 1020.30 (m)

IEC 60601-2-44: 2002, 29.201.5

IEC 60601-2-44: 2012, 203.7.1

IEC 60601-2-44: 2012, 203.7.3

Beam quality expressed as first Half Value Layer (HVL):

Tube voltage	Half Value Layer (HVL)	
80 kV	≥ 4.5 mm Al	(typical 5.3 mm)
110 kV	≥ 5.0 mm Al	(typical 7.1 mm)
130 kV	≥ 5.0 mm Al	(typical 8.1 mm)

Leakage technique factors:

≤ 0.8 mGy/h	1 m distance to focal spot with 130 kV, 3500 W

Minimum filtration:

CARE filter tube	Equivalent to 5.5 mm Al at 140 kV
CARE filter beam limiting device	0.5 mm Al

1.1.15 Stray radiation

According to:

IEC 60601-2-44: 2002, 29.208.101

IEC 60601-2-44: 2012, 203.13.2

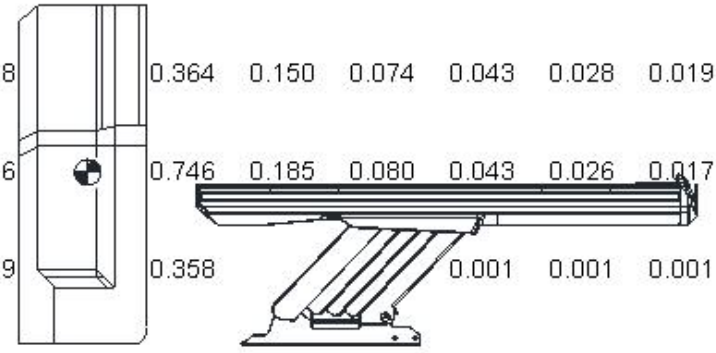
Stray radiation is indicated for the horizontal and vertical planes on the basis of the scanner coordinate system (intersection of scanner axis with scan plane) at maximum tube voltage (130 kV) and maximum total collimation width (38.4 mm).

A cylindrical PMMA phantom with a diameter of 32 cm and a length of 15 cm is centered in the scan plane for the stray radiation measurement. A 1000 cm^3 spherical dose chamber with 140mm diameter is used for the measurement.

The accuracy of stated value is determined by the accuracy of chamber positioning (±5 cm in each direction, which may lead to tolerances up to ±20%) and by the accuracy of the dosemeter (±5% or 0.004µGy/mAs, whichever is greater). Backscatter from cabin walls or similar surface may cause additional variation in the radiation measurement.

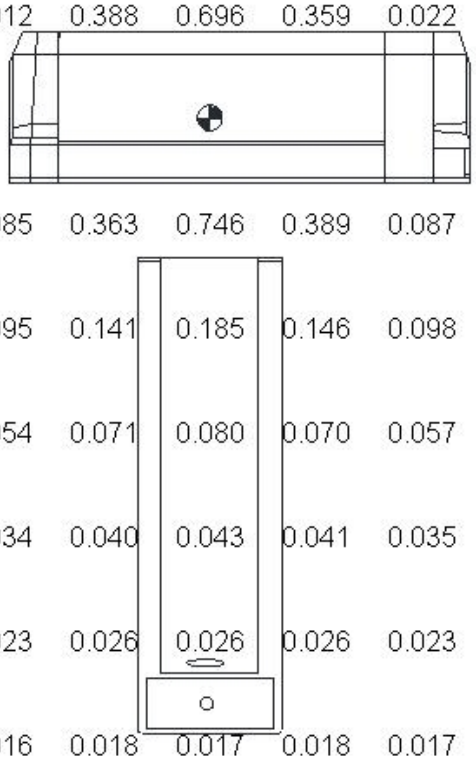
Stray radiation in microGray (µGy) per mAs:

	2.0m	1.5m	1.0m	0.5m	0m	0.5m	1.0m	1.5m	2.0m	2.5m	3.0m	3.5m
1.5m	0.030	0.040	0.025	0.004	0.004	0.011	0.055	0.044	0.032	0.023	0.017	0.013
1.0m	0.036	0.056	0.088	0.019	0.004	0.076	0.094	0.059	0.038	0.026	0.019	0.014
0.5m	0.042	0.071	0.139	0.348		0.364	0.150	0.074	0.043	0.028	0.019	0.014
0m	0.043	0.075	0.172	0.696		0.746	0.185	0.080	0.043	0.026	0.017	0.016
0.5m	0.039	0.067	0.129	0.329		0.358			0.001	0.001	0.001	0.001



Stray radiation (vertical)

	1.5m	1.0m	0.5m	0m	0.5m	1.0m	1.5m
2.0m	0.030	0.036	0.041	0.043	0.041	0.037	0.030
1.5m	0.041	0.059	0.071	0.075	0.071	0.057	0.042
1.0m	0.029	0.093	0.144	0.172	0.141	0.093	0.031
0.5m	0.003	0.012	0.388	0.696	0.359	0.022	0.003
0m	0.003						0.002
0.5m	0.010	0.085	0.363	0.746	0.389	0.087	0.013
1.0m	0.052	0.095	0.141	0.185	0.146	0.098	0.057
1.5m	0.041	0.054	0.071	0.080	0.070	0.057	0.043
2.0m	0.029	0.034	0.040	0.043	0.041	0.035	0.029
2.5m	0.020	0.023	0.026	0.026	0.026	0.023	0.021
3.0m	0.015	0.016	0.018	0.017	0.018	0.017	0.015
3.5m	0.011	0.012	0.013	0.016	0.013	0.012	0.012



Stray radiation (horizontal)

1.1.16 Performance specification of automatic exposure controls

According to:

IEC 60601-2-44: 2012, 203.106

The CT scanner offers different types of automatic exposure controls for adaptation of the exposure to the individual patient.

- CARE Dose 4D: mAs adaptation to patient size, longitudinal, and angular tube current modulation
- ECG-Pulsing: Adaptation of tube current to the patient's ECG signal

The modulation type applied depends on the protocol selected and the individual setting:

Modulation types for automatic exposure controls:

Protocol types, organ characteristics	Modulation type	
Abdomen AngioBody Pediatric Head Pediatric Angio Head Neck Pelvis Shoulder Spine Thorax	XYZ exposure control (CARE Dose 4D)	The tube current is adapted to the patient size. It is varied along the z-axis according to the patient's attenuation profile and modulated angularily according to the patient's angular attenuation profile that has been measured online.
Adult Head Adult Angio Head	Z exposure control (CARE Dose 4D)	The tube current is adapted to the patient size and varied along the z-axis according to the patient's attenuation profile.
Body-Perfusion Extremities	XY exposure control (CARE Dose)	The tube current is modulated angularily according to the patient's angular attenuation profile that has been measured online and is based on the user-selected mAs.
Osteo	Fixed exposure control (CARE Dose 4D)	The tube current is adapted to an average patient size and kept constant.
Cardio Respiratory (Z exposure control for chest pain protocols only)	ECG-Pulsing Combined with fixed exposure control (CARE Dose4D)	The tube current is adapted to an average patient size and pulsed according to the patient's ECG signal.

CARE Dose/CARE Dose 4D

CARE Dose 4D automatically adapts the tube current to the patient's body size and shape.

Using the patient's topogram, CARE Dose4D evaluates two profiles of the patient's X-ray attenuation in the a.p. and lateral directions.

Based on these profiles, the mAs value is adapted to the patient during the subsequent CT scans. The adaption follows an adaptation curve, which determines the correlation between X-ray attenuation and tube current. The adaptation curve has been derived from the clinical optimization for constant diagnostic image quality.

The adaptation curve is based on three parameters:

- A reference X-ray attenuation, related to a typical adult patient size of approximately 70-80 kg, are internally stored in the CT system for the considered organ characteristics and depending on the selected protocol.

Reference attenuation values for the Automatic Exposure Control:

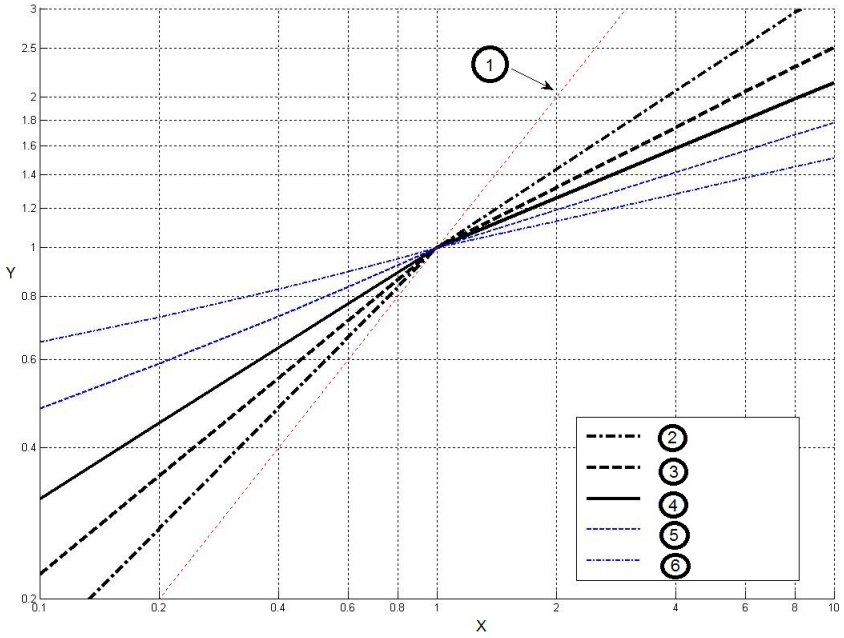
Organ characteristic	Reference X-ray attenuation
Head, Angio Head	50

Organ characteristic	Reference X-ray attenuation
Neck	100
Shoulder	1200
Thorax, Respiratory	600
Cardio	400
Abdomen, Angio Body, Body Perfusion	1000
Pelvis, Osteo	1500
Spine	800
Extremities	500

- A reference mAs value “ref. mAs” (or “ref. mAs/rot”), which is adjustable by the operator on the Scan Card to modify the overall dose and image quality of the scan range.
- An adjustment of the adaptation strength, which can be selected in five steps (very weak, weak, average, strong, very strong), is provided to configure the adaption for body sizes smaller or larger than the reference body.

The curve below shows the theoretical adaptation curve for a cylindrical body shape. Depending on the individual patient geometry, the curve may deviate from this theoretical function. Moreover, the curve may be cut depending on the system’s power limit.

Depending on the modulation type of the protocol, the patient size adapted tube current can be fixed, modulated along the z-axis according to the adaption curve, modulated according to the patient’s online measured angular attenuation profile (CARE Dose), or combination of these.



Adaption of mAs to patient attenuation with adjustable strengths

x Patient attenuation relative to reference attenuation

y mAs relative to ref. mAs

(1) contrast noise

(2) very strong

(3) strong

(4) average

(5) weak

(6) very weak

Guidance on the Use of Radiation Shields to Reduce Patient Dose in CT scanning

In general the effects of radiation shields used in CT examinations on patient dose and image quality depend on several factors, in particular the material and shape of the radiation shield, its placement and the patient's body shape. Since these factors vary with each individual examination setup, a generalized and scientifically validated statement is not feasible.

However, the following statements may provide a better understanding of the situation.

- **Radiation shield positioned outside of the directly exposed range of a CT scan and the corresponding topogram scan:**

  No negative influence on image quality and patient dose, therefore, no concerns in using radiation shields in this situation.

- **Radiation shield positioned within the directly exposed range of a CT scan or the corresponding topogram scan:**

  Shielding may affect image quality and patient dose.

  - Image reconstruction algorithms widely suppress artifacts caused by metals in or on the patient's body but artifacts cannot generally be excluded.
  - Siemens' automatic exposure control, CARE Dose 4D, can be substantially affected by the patient's body. To minimize a potential negative effect of Radiation Shields it is recommended to scan the Topogram without shields and use the shields only during the subsequent CT examination.
  - While patient dose is reduced in areas protected by the radiation shield, consequently the image noise may increase (in addition to the presence of artifacts) and affect diagnosis.
  - An alternative to shielding that also only locally reduces the radiation dose in the patient is a dedicated scan mode like X-CARE that is offered on most of the CT systems manufactured by Siemens Healthcare.

In summary, the use of radiation shields positioned within the directly exposed range of a CT scan cannot generally be recommended. Patient dose and image quality must be taken into consideration.

ECG Gating

The tube current is synchronized to the patient's ECG signal and gated depending on the user defined setting for the image time window, which is set as a percentage range of the RR interval (e.g. 70% to 70%). Outside the tube current gating window the tube current is reduced to 20% of the value inside the gating window.

1.2 Image quality

1.2.1 Low-contrast detectability

Low contrast detectability has been measured in a body mode at 130 kV with the following parameter settings: 10 mm slice, kernel B20s, FoV 150 mm with a 20 cm Catphan consisting of a plastic disc with rod inserts of different size and contrast. The phantom is positioned approximately 2 cm of the plane to avoid the ring suppression algorithm to diminishing the contrast of the concentrically positioned inserts.

The low contrast detectability is determined by the visual inspection of the images. The specified low contrast is the smallest diameter that can be visualized for a certain contrast at the specified dose.

This method is subjective and depends on the viewer's visual acuity and on statistical fluctuations of the image noise. Therefore, the stated diameter combines the evaluation of several human observers and several images with same scan parameters.

Due to the high variability of these results it is difficult to objectively measure low contrast detectability. Hence, this visual method is not recommended for an Acceptance Test.

$CTDI_{vol}$ (32 cm) for low-contrast detectability of 5 mm / 3 HU in 20 cm Catphan for 10 mm slice:

	CTDIvol (32 cm)	Collimation
Sequence	8.86 mGy	1 × 10.0 mm

1.2.2 CT number

According to:

IEC 60601-2-44: 2012, 203.6.7.2

The CT number is specified for air (-1000 ± 4 HU) and water (0 ± 4 HU) only. The specification is not valid for other materials in the beam. The CT number for water is valid for a cylindrical phantom with a diameter ranging from 20 cm to 30 cm, and that is centered, and aligned with the scanner axis.

The CT-numbers for other materials depend on the kV settings.

1.2.3 Uniformity

According to:

IEC 60601-2-44: 2012, 203.6.7.2

The uniformity of the CT values is specified for a typical scan mode within a cylindrical 20 cm water phantom that has been centered in the scan plane without any other objects in the scan field.

Nominal MTF values of a wire place in plastics:

Cross-field uniformity (maximum)	≤ 4 HU	Typical mode, 20 cm water phantom
Cross-field uniformity (typical)	≤ 2 HU	Typical mode, 20 cm water phantom

1.2.4 Image noise

According to:

21 CFR 1020.33 (c)(3)(i), (c)(3)(v)

IEC 60601-2-44: 2009, 203.6.7.2

IEC 60601-2-44: 2012, 203.6.7.2

A circular Region of Interest (ROI) with a diameter of approximately 40% of the phantom diameter was used to measure the noise in images of a 20 cm and 30 cm water phantom using the typical head and typical body conditions of operation.

Image noise:

	Ø 20 cm water phantom	Ø 30 cm water phantom
Typical adult head	3.16 HU ± 10%	-
Typical adult body	4.71 HU ± 10%	11.86 HU ± 10%

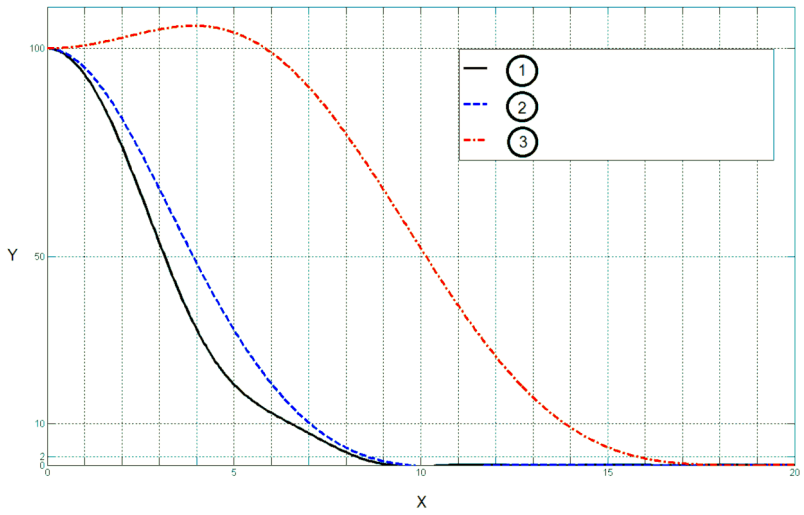
1.2.5 High-Contrast-Resolution, Modulation Transfer Function (MTF)

According to:

21 CFR 1020.33 (c)(3)(ii), (c)(3)(v)

IEC 60601-2-44: 2012, 203.6.7.2

The Point Spread Function (PSF) image is obtained by scanning a 0.1 mm tungsten wire placed in plastic. The two-dimensional Fourier transformation of the PSF generates a Modulation Transfer Function (MTF) of the system.



Measured MTF of an image of a wire placed in plastics

x Spatial frequency [LP/cm]

y MTF [%]

(1) Typical Head (H31s)

(2) Typical Body (B41s)

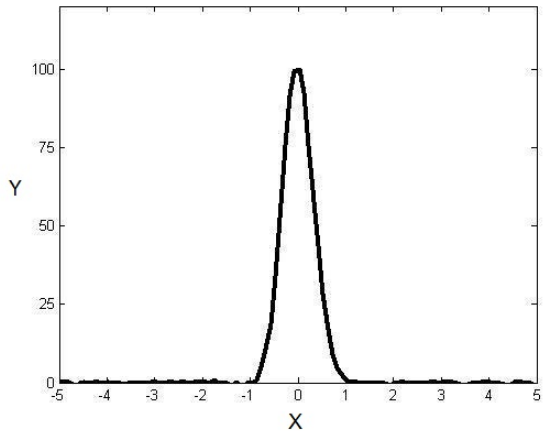
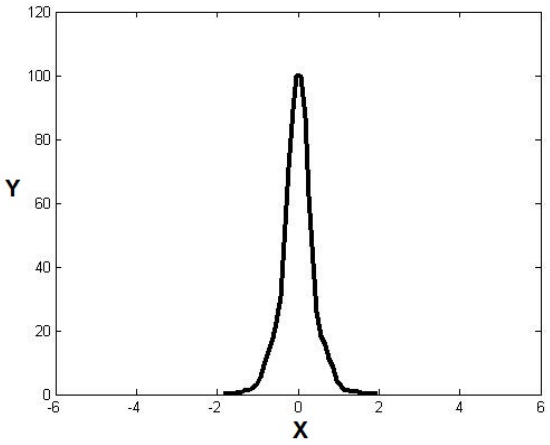
(3) Sharpest (U90s)

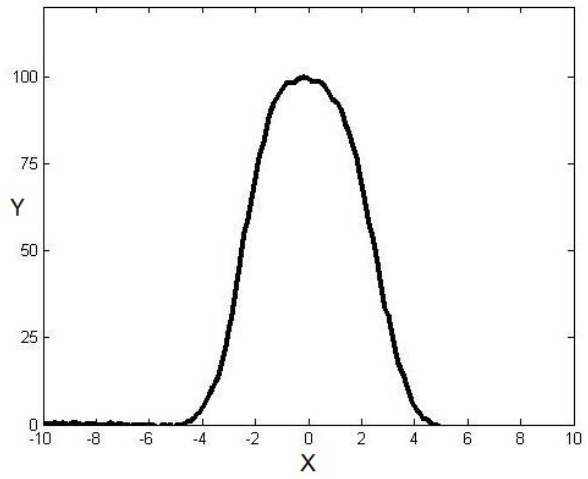
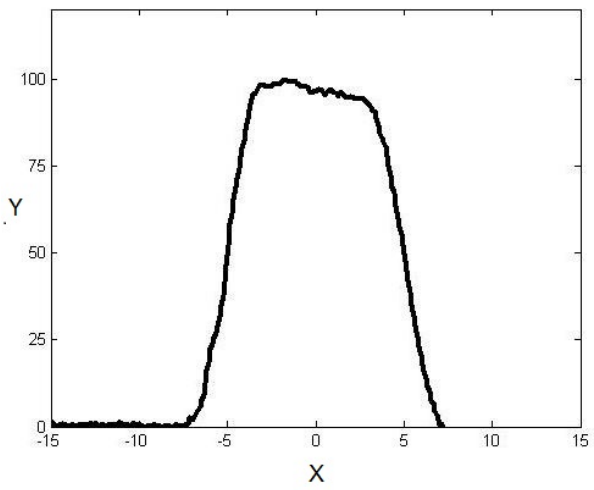
Low contrast detectability:

MTF	Typical Head (H31s)	Typical Body (B41s)	Sharpest (U90s)
50%	3.08 LP/cm ± 10%	3.85 LP/cm ± 10%	10.09 LP/cm ± 10%
10%	6.50 LP/cm ± 10%	7.02 LP/cm ± 10%	13.80 LP/cm ± 10%
2%	8.31 LP/cm ± 10%	8.56 LP/cm ± 10%	15.82 LP/cm ± 10%

1.2.6 Sensitivity profiles

Slice sensitivity profiles (SSP) were measured on the basis of images of a thin air slit that was moved through the scan plane along the z-axis in very small steps and imaged after each scan in a single axial scan. The sensitivity profile is the profile of relative HU values measured along the z-direction at the location of the air slit in the image. Sensitivity profiles are valid for head mode and body mode.

Thinnest axial slice	
	
x: z [mm] y: SSP [%]	x: z [mm] y: SSP [%]
Normial slice thickness 0.6 mm (with 0.6 mm slice thickness license)	**Normial slice thickness 0.75 mm (without 0.6 mm slice thickness license)**

Midrange axial slice	Maximum axial slice
	
x: z [mm] y: SSP [%]	x: z [mm] y: SSP [%]
Normial slice thickness 5 mm	Normial slice thickness 10 mm

1.2.7 Nominal tomographic section thicknesses

According to:

21 CFR 1020.33 (c)(3)(iii)

IEC 60601-2-44: 2009, 203.6.7.2

IEC 60601-2-44: 2012, 203.6.7.2

Nominal tomographic section thicknesses:

Application	Mode	Acquisition (mm)	Reconstructable Slice Width (mm)																		
			0.6 *	0.75	1.0	1.2	1.5	2.0	2.4	3.0	4.0	4.8	5.0	6.0	7.0	7.2	8.0	9.6	10	15	19.2	20
Routine	Spiral	64 x 0.6, 32 × 0.6, 12 × 0.6, 4 × 0.6	x	x	x		x	x		x	x		x	x	x		x		x			
		32 × 1.2					x	x		x	x		x	x	x		x		x			
	Sequence	32 × 1.2						x		x	x		x	x	x		x		x			
		64 x 0.6			x		x	x		x	x		x	x	x		x		x			
		32 × 0.6			x		x	x		x	x		x	x	x		x		x			
		12 × 0.6			x		x	x		x	x		x									
		4 × 0.6		x	x		x	x														

* Not applied for system without 0.6 mm slice thickness license

a) For Multi-scan only

b) For Respiratory only

c) For CAREVision only

d) Preset for CareVision 32 x 0.6 mm acquisition, not configurable

e) Depending on scan protocol selections, not all combinations shown are selectable

1 Dosimetry and imaging performance report (128-slice and 64-row/64-slice)

Application	Mode	Acquisition (mm)	Reconstructable Slice Width (mm)																		
			0.6 *	0.75	1.0	1.2	1.5	2.0	2.4	3.0	4.0	4.8	5.0	6.0	7.0	7.2	8.0	9.6	10	15	19.2	20
Thorax HR Seq	Sequence	2 × 1			x			x														
		1 × 2						x														
Cardio Respiratory	Spiral	64 x 0.6, 32 × 0.6	x	x	x		x	x		x	x		x									
		32 × 1.2					x	x		x	x		x									
	Sequence	32 × 1.2						x		x	x		x	x[b]	x[b]		x[b]		x[b]			
		64 x 0.6, 32 × 0.6			x		x	x		x	x		x	x[b]	x[b]		x[b]		x[b]			
		12 × 0.6			x		x	x		x	x		x									
		4 × 0.6		x	x		x	x														
CAREVision Biopsy	Sequence	64 × 0.6																			x[c]	
		1 × 10																	x			
		32 × 0.6										x[d]				x		x[c]				
		12 × 0.6							x													
		1 × 2						x														
Perfusion	Spiral	64 x 0.6, 32 × 0.6, 12 × 0.6, 4 × 0.6	x	x	x		x	x		x	x		x	x	x		x		x			
		32 x 1.2					x	x		x	x		x	x	x		x		x			
	Multiscan or Sequence[e]	32 × 1.2						x		x	x		x	x	x		x		x	x[a]		x[a]
		64 × 0.6			x		x	x		x	x		x	x	x		x		x	x [a]		x [a]
		32 × 0.6			x		x	x		x	x		x	x	x		x		x	x[a]		
		12 × 0.6			x		x	x		x	x		x									
		4 × 0.6		x	x	x	x	x	x													
		1 × 10																	x			
		2 × 5											x						x			
		1 × 2						x														
		2 × 1			x			x														
TestBolus	Sequence	1 × 10																	x			
		2 × 5											x						x			
		1 × 2						x														
		2 × 1			x			x														
		4 × 0.6	x			x			x													

*** Not applied for system without 0.6 mm slice thickness license**

a) For Multi-scan only

b) For Respiratory only

c) For CAREVision only

d) Preset for CareVision 32 x 0.6 mm acquisition, not configurable

e) Depending on scan protocol selections, not all combinations shown are selectable

According to 21 CFR 1020.33 (c)(3)(v)

Tolerances of slice thickness:

0.6 mm	Tolerance: ± 0.3 mm
0.75 mm	Tolerance: ± 0.5 mm
1 - 2 mm	Tolerance: ± 50 %
> 2 mm	Tolerance: ± 1.0 mm

2 Dosimetry and imaging performance report (64-slice)

This chapter provides dose and imaging performance data. The data is in accordance with the US code of federal regulations 21 CFR 1020.33 (c) and the standard of the International Electrotechnical Commission IEC 60601-2-44.

This chapter provides the following information:

- $CTDI_{100}$ for typical CT conditions of operation with regard to typical head, body, cardiac, head perfusion and pediatric body modes
- Dose factors showing the relative changes of $CTDI_{100}$ compared to the $CTDI_{100}$ of each typical mode in varying a scan parameter
- Dosimetry data, such as beam quality, dose profiles, and stray radiation tables
- Image noise and High-Contrast-Resolution (HCR) of the typical modes
- Homogeneity of CT values and low-contrast resolution
- Reconstructable slice thicknesses

2.1 Dose information

2.1.1 General information about dose indication

The CT system provides information about the $CTDI_{vol}$ and Dose Length Product (DLP) as defined by the IEC 60601-2-44 standard. Both values are displayed on the user interface of the scanner before and after each scan range. In addition, these values are stored in the Patient Protocol and the DICOM Structured Dose Report. The $CTDI_{vol}$ represents the average energy dose (expressed as Air KERMA) within a cylindrical PMMA phantom and is aligned with the scanner axis and centered in the scan plane. The phantom diameter to which the displayed $CTDI_{vol}$ refers depends on the default application of the used protocol.

In general, the values of the body region “Body” are also used for the body region “Neck” .

Child protocols are recommended for pediatric patients under the age of 12 years and with a normal body size. For child protocols, factors for conversion of the displayed $CTDI_{vol}$ and DLP for the 32 cm phantom to equivalent $CTDI_{vol}$ and DLP for the 16 cm phantom are stated.

The CTDI values given in this manual are valid for deactivated CARE Dose 4D , as the feature is not adapted to phantom measurements.

Further information regarding dose reduction functions is provided in the *syngo CT Instructions for use*.

2.1.2 Phantoms and methods

According to:

21 CFR 1020.33 (c)(3)(v)

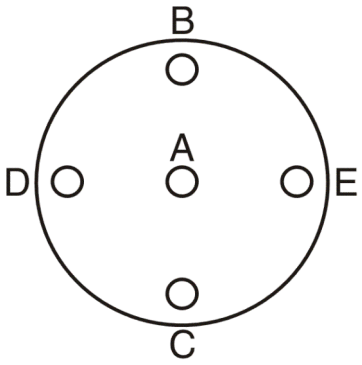
IEC 60601-2-44 (Ed. 3.1) 203.108

This chapter describes both phantoms and methods used to establish the dose values reported below. It also describes how to measure and determine $CTDI_{vol}$, in order to verify against the value displayed at the scanner.

The phantoms used to measure the CTDI values are circular cylinders of PMMA of diameter 16 cm (for head applications) or 32 cm (for body applications), and with a length of at least 14 cm. They contain holes parallel to the axis of the phantom (A – E) to hold 100 mm dose chambers.

Phantoms are aligned with the scanner axis and centered in the scan field. A dose chamber with an active length of 100 mm has been used for the dose measurements. All dose values are given in Air KERMA.

$CTDI_{100}$ is measured in the center (A) and peripheral drillings at 3 o'clock, 6 o'clock, 9 o'clock and 12 o'clock positions (B – E).



$CTDI_{100}$ locations in dosimetry phantoms with the line of sight towards the front side of the gantry

To ensure correct dose measurements, it is recommended to use a dosimeter conforming to IEC 61674. The dosimeter needs to be calibrated with beam qualities suitable for the CT energy spectrum examined, for example, CT beam qualities "RQT" according to IEC 61267.

The dose is measured in single axial scans, which enables the dose chamber to measure the integrated dose profile along the z-direction over 10 cm, centered to the scan plane. The magnitude of the measured values should lay above the accuracy of the dosimeter. Therefore, it may be necessary to select a reasonably large tube current and exposure time or to average the dosimeter readings over several scans. For measurements with the dose chamber in one of the peripheral positions of the phantom, averaging over several scans is highly recommended, otherwise the measured values may be distorted by the position of the scan start angle.

IEC 61674: 2012

'Medical electrical equipment – Dosimeters with ionization chambers and/or semiconductor detectors as used in X-ray diagnostic imaging'

IEC 61267: 2005

'Radiation conditions for use in the determination of characteristics'

To calculate the $CTDI_{100}$ from the dosimeter readings (usually displayed as dose integrated over z-direction, i.e., as Length-Dose-Product (DLP), for example in mGy·cm³) the value has to be divided by the nominal beam collimation. The nominal beam collimation is equal to the acquisition displayed at the scanner's console (for example. Acquisition 32 × 0.6 mm = 1.92 cm).

$$CTDI_{100} = \frac{1}{N \times T} \cdot \int_{-50\,mm}^{+50\,mm} D(z)\ dz = \frac{LDP}{NxT}$$

LDP – measured Length-Dose-Product [mGy·cm]

Note that the reading may also be displayed as dose averaged over the chamber length, e.g. in mGy.

NxT – Nominal Beam Collimation [cm]

This is valid for all nominal beam collimations ≤ 4 cm.

The $CTDI_w$ is the sum of a third of the $CTDI_{100}$ measured in the phantom's central chamber position ($CTDI_{100}^c$) and two thirds of the average of $CTDI_{100}$ measured in the phantom's four peripheral chamber position ($CTDI_{100}^p$).

$$CTDI_w = {}^1/_3 \cdot CTDI_{100}^c + {}^2/_3 \cdot \overline{CTDI_{100}^p}$$

According to it's definition, $CTDI_w$ needs to be derived from $CTDI_{100}$ measured in single axial scans. In this situation the $CTDI_{vol}$ is equal to the $CTDI_w$.

In general, the $CTDI_{vol}$ displayed is derived from the $CTDI_w$ by multiplication with a factor that takes into account the table feed during scanning:

For spiral scanning	$CTDI_{vol} = \frac{CTDI_w}{p}$
For axial scanning	$CTDI_{vol} = CTDI_w \cdot \frac{NxT}{v_f}$
For axial scanning without table feed	$CTDI_{vol} = n \cdot CTDI_w$
CT_p – Pitch factor **NxT – Nominal collimation** **v_f – Table feed per scan**	

2.1.3 Typical CT conditions of operation

According to:

21 CFR 1020.33 ©)(1)

IEC 60601-2-44: 2002, 29.1.102.1

IEC 60601-2-44: 2012, 203.109.1

The following table provides scan parameter settings for typical modes of operation according to the default setting of the Siemens scan protocols (with deactivated CARE Dose 4D).

Typical CT conditions of operation:

Application type	Typical Head	Typical Body	Typical Cardiac	Typical Head Perfusion	Typical Pediatric Body
Patient type	Adult	Adult	Adult	Adult	Child
Scan type	Sequence	Spiral	Sequence	Multiscan	Spiral
Protocol name	HeadSeq	Abdomen Routine	CaScore	NeuroPCT	Abdomen Routine
Tube voltage	130 kV	130 kV	130 kV	80 kV	110 kV
Tube current time product	200 mAs	120 eff. mAs	30 mAs/rot	150 mAs	98 eff. mAs
Tube current	100 mA	120 mA	74 mA	150 mA	229 mA
Rotation time	1 s	0.6 s	0.48 s	1 s	0.6 s
Number of scans	8	1	4	1	1
Scan time	2 s	11.6 s	0.4 s	40 s	3.4 s
Scan length	132.7 mm	200 mm	135.1 mm	0 mm	200 mm
Pitch factor or table feed	17.2 mm	0.6	34.5 mm	0	1.4
Collimation	32 × 0.6 mm	32 × 0.6 mm	32 x 1.2 mm	32 × 1.2 mm	32 × 1.2 mm
Data acquisition	32 × 0.6 mm	32 × 0.6 mm	32 x 1.2 mm	32 × 1.2 mm	32 × 1.2 mm
Total collimation	19.2 mm	19.2 mm	38.4 mm	38.4 mm	38.4 mm
Reconstructed slice width	5 mm	5 mm	3 mm	10 mm	5 mm
Kernel	H31s	B41s	B35s	H31s	B41s

2.1.4 $CTDI_{100}$ value for typical CT conditions of operation

According to:

21 CFR 1020.33 (c)(2)(i)

IEC 60601-2-44: 2002, 29.1.102.1(a)

IEC 60601-2-44: 2012, 203.109.1(a)

The following table indicates the CTDI values for typical modes specified in (➔ Page 8 *Phantoms and methods*)

There is no significant difference in the exposure of the peripheral chamber positions. The stated dose chamber positions are B - E according to their positions in the phantom (up, down, left, and right). See (➔ Page 8 *Phantoms and methods*)

$CTDI_{100}$ values of the typical CT conditions of operation:

Application type	Typical Head	Typical Body	Typical Cardiac	Typical Head Perfusion	Typical Body
Patient size	Adult	Adult	Adult	Adult	Child
CTDI phantom	Ø 16 cm	Ø 32 cm	Ø 32 cm	Ø 16 cm	Ø 32 cm
$CTDI_{100}$ [mGy]	per scan	per rotation	per scan	per scan	per rotation

Application type	Typical Head	Typical Body	Typical Cardiac	Typical Head Perfusion	Typical Body
Patient size	Adult	Adult	Adult	Adult	Child
Chamber position A (central) [mGy]	48.3	5.4	2.1	367.6	6.2
Chamber position B (Up) [mGy]	50.7	10.2	3.9	410.3	12.2
Chamber position C (down) [mGy]	50.8	10.1	3.9	410.3	11.9
Chamber position D (left) [mGy]	50.2	10.0	3.9	402.8	12.0
Chamber position E (right) [mGy]	49.4	10.1	3.9	394.1	12.2
Average peripheral [mGy]	50.3	10.1	3.9	404.4	12.1
$CTDI_w$ [mGy]	49.6	8.5	3.3	392.1	10.1
$CTDI_{vol}$ [mGy]	55.4	14.2	3.7	392.1	7.2

2.1.5 Dose factors related to the $CTDI_{100}$ for typical CT conditions of operation

According to:

21 CFR 1020.33 (c)(2)(ii)

21 CFR 1020.33 (c)(2)(iii)

IEC 60601-2-44: 2002, 29.1.102.1(b), (c)

IEC 60601-2-44: 2012, 203.109.1(b), (c)

The system provides one permanent shaped X-ray beam filter as default settings for all applications, so the $CTDI_{100}$ is influenced by the following selectable scan parameters:

- kV
- Acquisition
- mAs values (mAs, eff. mAs, mAs/rot)

The $CTDI_{100}$ is not influenced by the rotation time or recon parameters, such as Kernel or FoV.

In the following tables, the $CTDI_{100}$ for the typical mode is represented by the value 1.00, shown in bold. $CTDI_{100}$ for varying scan parameters are given as a proportion of the $CTDI_{100}$ for the typical mode.

Dose factors related to the $CTDI_{100}$ for varying tube voltage:

Tube voltage		Typical Head	Typical Body	Typical Cardiac	Typical Head Perfusion	Typical Pediatric Body
		CTDI Phantom Ø 16 cm	CTDI Phantom Ø 32 cm	CTDI Phantom Ø 32 cm	CTDI Phantom Ø 16 cm	CTDI Phantom Ø 32cm
80 kV	Central	0.27	0.22	0.22	**1.00**	0.34
	Peripheral	0.29	0.26	0.26	**1.00**	0.39
	Weighted	0.28	0.25	0.26	**1.00**	0.38
110 kV	Central	0.69	0.65	0.65	2.53	**1.00**
	Peripheral	0.70	0.68	0.68	2.43	**1.00**
	Weighted	0.69	0.67	0.67	2.46	**1.00**
130 kV	Central	**1.00**	**1.00**	**1.00**	3.66	1.54
	Peripheral	**1.00**	**1.00**	**1.00**	3.48	1.48
	Weighted	**1.00**	**1.00**	**1.00**	3.54	1.49

Dose factors related to the $CTDI_{100}$ for varying acquisition type:

Acquisition	Typical Head	Typical Body	Typical Cardiac	Typical Head Perfusion	Typical Pediatric Body
2 × 1 mm	1.61	1.61	1.73	1.75	1.70
4 × 0.6 mm	1.34	1.34	1.44	1.46	1.42
12 × 0.6 mm	1.21	1.21	1.30	1.30	1.31
2 × 5 mm	0.87	0.87	0.94	0.94	0.94
32 × 0.6 mm	**1.00**	**1.00**	1.08	1.08	1.08
32 × 1.2 mm	0.93	0.93	**1.00**	**1.00**	**1.00**

Dose factors related to the $CTDI_{100}$ for varying mAs:

Dose factors are valid for deactivated CARE Dose4D.

Current	Typical Head		Typical Body		Typical Cardiac		Typical Head Perfusion		Typical Pediatric Body	
	mAs	factor	eff. mAs	factor	mAs	factor	mAs/rot	factor	eff. mAs	factor
25 mA	50	0.25	25	0.21	10	0.34	25	0.17	11	0.11
74 mA	148	0.74	74	0.61	30	**1.00**	74	0.49	32	0.32
100 mA	200	**1.00**	100	0.83	41	1.36	100	0.67	43	0.44
120 mA	240	1.20	120	**1.00**	49	1.63	120	0.80	51	0.52
150 mA	300	1.50	150	1.25	61	2.03	150	**1.00**	64	0.66
229 mA	457	2.29	229	1.91	93	3.10	229	1.52	98	**1.00**
345 mA	690	3.45	345	2.88	140	4.68	345	2.30	148	1.51

2.1.6 Dose levels causing deterministic radiation effects

According to:

IEC 60601-1-3: 2008, 5.2.4.5+Annex A.2

IEC 60601-2-44: 2012, 203.5.2.4.5,

Certain modes of operation allow selections of scan parameters that may lead to an accumulated peripheral $CTDI_{100}$ of more than 1 Gy. This dose may exceed the threshold for deterministic radiation effects on the patient's skin or eye lenses (see IEC 60601-1-3:2008, Annex A.2, 5.2.4.5).

The accumulated peripheral $CTDI_{100}$ may serve as a rough estimation of skin or eye lens dose. However other factors may influence the dose to cause deterministic radiation effects, for example:

- A deviation of the patient's body diameter from the standard CTDI phantom size may lead to a patient's skin dose that is noticeably higher than indicated by the accumulated peripheral $CTDI_{100}$. Such a deviation may occur, for example, if a body perfusion examination is performed with a very thin patient.
- Using the scan protocol dedicate to body scans to perform head scan (for which the dose estimation should be based on Φ16 cm), may lead to a patient skin dose that is great higher than common estimation.
- Repeating examinations within a short time period (compared to the biological recovery time for deterministic radiation effects) may lead to deterministic radiation damages, even if the accumulated peripheral $CTDI_{100}$ of the single examinations was below 1 Gy.

In general, the accumulated peripheral $CTDI_{100}$ can be derived from the displayed $CTDI_{vol}$ by multiplying the $CTDI_{vol}$ with a given factor that depends on tube voltage.

Ratio of peripheral $CTDI_{100}$ to displayed $CTDI_{vol}$:

Tube voltage	Typical Head Ø 16 cm	Typical Body Ø 32 cm
80 kV	1.0	1.2
110 kV	1.0	1.2
130 kV	1.0	1.2

By using the default Siemens scan protocols for patients with a standard patient size, without changing the default settings of the scan parameters, and without repeating the scans, the accumulated peripheral $CTDI_{100}$ will be kept reasonably below 1 Gy.

The following list gives examples of situations that may lead to an accumulated peripheral $CTDI_{100}$ of 1.0 Gy and above (numbers are approximations). The list refers to default Siemens scan protocols and concentrates on scan modes with relatively high radiation exposure. This list is not exhaustive.

- Use of perfusion protocols with changes in kV, scan times, or mAs, for example:
  - *Neuro PCT* with tube voltage changed from 80 kV to 130 kV (≈ 1.4 Gy)
  - *Neuro PCT* with scan time increased from 40 s to ≈ 100 s
  - *Neuro PCT* with mAs increased from 150 mAs to ≈ 371 mAs
- Scanning of sequence protocols without table feed, for example:
  - Approximately 20 scans of *Head Neuro Seq* without table feed
- Repeating standard sequences or spiral scans within an examination, for example:
  - Repeating application of the default protocol *Head Neuro Seq* (approximately 20 times)
  - Repeating application of the default protocol *Abdomen Routine* (approximately 61 times)
- Use of CARE Vision protocol (without Hand CARE) for Head intervention*
  - By applying 130 kV/130 mA for scan time ≈ 24 s
  - Make 15 s scan with 130 kV by applying mAs ≈ 207 mAs

*) The case may happen according to above hint.

To prevent unintended, excessive exposure, the CT system provides tools for Dose Notification and Dose Alert. The default threshold value for Dose Alert is an accumulated $CTDI_{vol}$ of 1.0 Gy.**

**) In case of applying body scan protocols for thin patients, small children or head examinations, the actual exposure dose may be underestimated. Special calculation need to be applied to prevent excessive exposure even the displayed accumulated $CTDI_{vol}$ is still below 1.0 Gy threshold.

2.1.7 Overview of $CTDI_{100}$ values (mGy/100mAs)

Phantom: Ø 16 cm Application: Routine head							
Voltage	Collimation [mm]	2 x 1	4 x 0.6	12 x 0.6	2 x 5	32 x 0.6	32 x 1.2
	Total [mm]	2.0	2.4	7.2	10.0	19.2	38.4
80 KV	$CTDI_{100}$, central	10.66	8.88	7.95	5.72	6.60	6.10
	$CTDI_{100}$, peripheral	11.75	9.80	8.74	6.29	7.24	6.71
	CTDIw	11.39	9.49	8.48	6.10	7.02	6.51
110 KV	$CTDI_{100}$, central	26.18	21.81	20.06	14.44	16.65	15.42
	$CTDI_{100}$, peripheral	27.70	23.08	21.19	15.26	17.55	16.31
	CTDIw	27.19	22.66	20.81	14.99	17.25	16.01
130 KV	$CTDI_{100}$, central	38.89	32.41	29.06	20.92	24.17	22.30
	$CTDI_{100}$, peripheral	40.58	33.81	30.39	21.88	25.15	23.39
	CTDIw	40.01	33.35	29.95	21.56	24.82	23.02

Phantom: Ø 32 cm Application: Adult body, Pediatric body*							
Voltage	Collimation [mm]	2 x 1	4 x 0.6	12 x 0.6	2 x 5	32 x 0.6	32 x 1.2
	Total [mm]	2.0	2.4	7.2	10.0	19.2	38.4
80 KV	$CTDI_{100}$, central	2.67	2.22	1.98	1.43	1.64	1.51
	$CTDI_{100}$, peripheral	5.96	4.97	4.49	3.24	3.68	3.45
	CTDIw	4.87	4.05	3.66	2.63	3.00	2.80
110 KV	$CTDI_{100}$, central	7.67	6.39	5.87	4.23	4.85	4.49
	$CTDI_{100}$, peripheral	14.98	12.49	11.54	8.31	9.53	8.82
	CTDIw	12.55	10.45	9.65	6.95	7.97	7.38
130 KV	$CTDI_{100}$, central	12.07	10.06	9.06	6.52	7.49	6.93
	$CTDI_{100}$, peripheral	22.52	18.76	17.00	12.24	14.01	13.03
	CTDIw	19.03	15.86	14.35	10.33	11.83	11.00
*) See for necessary conversion for pediatric body if necessary.							

No phantom Free air							
Voltage	Collimation [mm]	2 x 1	4 x 0.6	12 x 0.6	2 x 5	32 x 0.6	32 x 1.2
	Total [mm]	2.0	2.4	7.2	10.0	19.2	38.4
80 KV		19.30	16.08	14.32	10.31	11.85	11.04
110 KV		40.62	33.97	31.15	22.43	25.83	24.18
130		57.85	48.21	43.29	31.17	35.98	33.57

2.1.8 Tolerances for CTDI

According to:

21 CFR 1020.33

IEC 60601-2-44: 2002, 29.1.102.1(d)

IEC 60601-2-44: 2002, 50.101

IEC 60601-2-44: 2012, 203.109.1(d)

IEC 60601-2-44: 2012, 201.12.1.101

IEC 60601-2-44: 2012, Amd.1 203.112

The actual exposure values, such as $CTDI_{100}$, $CTDI_{w}$, $CTDI_{vol}$ and DLP, may deviate from the values displayed at the scanner and from the values stated in this manual.

Tolerances for CTDI values:

	Typical deviation	Max. tolerance
80 kV	within ± 15%	± 40%
110 kV, 130 kV	within ± 15%	± 30%

The linearity of the radiation output (linearity of measured dose related to displayed mAs) is ± 10%.

2.1.9 Conversion factor for $CTDI_{vol}$ for pediatric protocols from Ø 32 cm phantom to Ø 16 cm phantom

The displayed and reported $CTDI_{vol}$ and DLP refers to cylindrical PMMA phantoms of a diameter of 16 cm for head application and of a diameter of 32 cm for body applications (adult and pediatric protocols), according to IEC 60601-2-44.

Since a child's body diameter may typically be better represented by a 16 cm phantom than by a 32 cm phantom, factors for the conversion of $CTDI_{vol}$ and DLP from a phantom size of 32 cm to a phantom size of 16 cm are given in the following table.

Conversion factor for $CTDI_{vol}$:

kV setting	Conversion factor from Ø 32 cm to Ø 16 cm
80 kV	2.3
110 kV	2.2
130 kV	2.1

For a typical pediatric body protocol at 110 kV, the displayed $CTDI_{vol}$ and DLP (related to the Ø 32 cm CTDI-phantom) are 7.23 mGy and 198.82 mGy × cm. For the same protocol, the $CTDI_{vol}$ and DLP of a Ø 16 cm CTDI-phantom are 2.2 times higher than the values of a Ø 32 cm CTDI-phantom, resulting in $CTDI_{vol}$ as 15.69 mGy and DLP as 431.68 mGy × cm.

2.1.10 $CTDI_{vol}$ for topograms

The $CTDI_{vol}$vol for topogram scans may be estimated according to IEC 60601-2-44, Annex B.

Since the collimation (4 × 0.6 mm) and table speed (100 mm/s) for the topogram is fixed, the $CTDI_{vol}$ for topograms is stated in the following table depending on the kV and mA values.

$CTDI_{vol}$ for topograms:

Protocol type	Head	Body
Phantom size	Ø 16 cm	Ø 32 cm
	$CTDI_{vol}$ µGy/mA	$CTDI_{vol}$ µGy/mA
80 kV	2.3	1.0
110 kV	5.4	2.5
130 kV	8.0	3.8

2.1.11 $CTDI_{free\ air}$

According to:

IEC 60601-2-44, 203.109.2

The $CTDI_{free\ air}$ is stated in the following table based on the typical body mode (shown in bold type) for varying collimation, and kV. Additionally, the $CTDI_{free\ air}$ for the typical head mode is stated.

$CTDI_{free\ air}$ for setting of typical body (bold type) with variation of collimation and kV:

Collimation [mm]	Variation of the collimation					
	2 × 1	4 × 0.6	12 × 0.6	2 × 5	32 × 0.6	32 × 1.2
Total [mm]	2.0	2.4	7.2	10.0	19.2	38.4
80 kV	23.16 mGy	19.30 mGy	17.18 mGy	12.37 mGy	14.23 mGy	13.25 mGy
110 kV	48.74 mGy	40.77 mGy	37.38 mGy	26.92 mGy	31.00 mGy	29.01 mGy
130 kV	69.42 mGy	57.85 mGy	51.95 mGy	37.40 mGy	**43.17 mGy**	40.29 mGy

$CTDI_{free\ air}$ for setting of Typical Head:

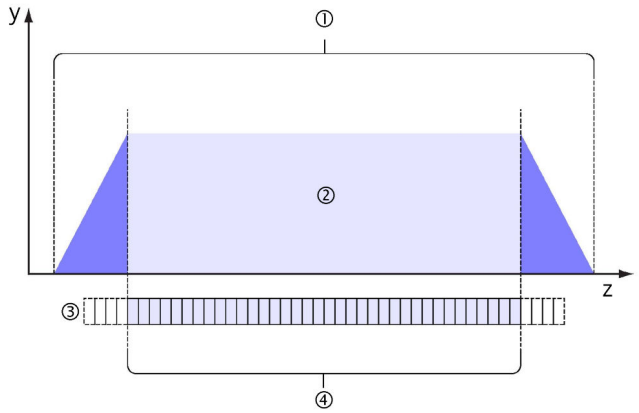
Collimation[mm]	32 × 0.6
Total [mm]	19.2
130 kV	**71.96 mGy**

2.1.12 Geometric efficiency in the z-direction

According to

IEC 60601-2-4: 2012 203.113

The dose efficiency is defined by IEC 60601-2-44 as the integral of the “free in air” in the isocenter along the z-axis over the acquisition range in the z-direction, expressed as percentage of the total integral of the dose profile in the z-direction. The acquisition range is the distance spanned by the selected detector elements along the z-axis. The displayed $CTDI_{vol}$ and DLP reflect the dose efficiency of a collimation according to the definition of $CTDI_{vol}$.



Correlation of dose profile and collimation regarding dose efficiency

y Dose

z z-axis

(1) Total dose profile width

(2) Dose profile

(3) Detector

(4) Acquisition range

Dose efficiencies for the various collimations:

Acquisition	Total collimation	Dose efficiency
32 × 1.2 mm	38.4 mm	91.5%
32 × 0.6 mm	19.2 mm	85.8%
12 × 0.6 mm	7.2 mm	71.1%
2 × 5 mm	10.0 mm	96.8%
1 × 10 mm	10.0 mm	96.8%
4 × 0.6 mm	2.4mm	**64.1%**
2 × 1 mm	2.0 mm	**64.1%**
1 × 2 mm	2.0mm	**64.1%**

For CT scans with a dose efficiency lower than 70%, a message containing information about the dose efficiency is displayed after the loading of a scan range. The user has to confirm the message before starting the scan.

2.1.13 Dose profiles

According to:

21 CFR 1020.33 (c)(2)(iv)

21 CFR 1020.33 (c)(3)(iv)

21 CFR 1020.33 (c)(3)(v)

IEC 60601-2-44: 2012 29.1.103.1

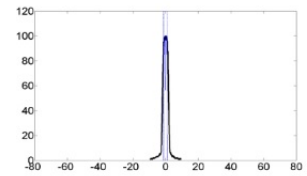
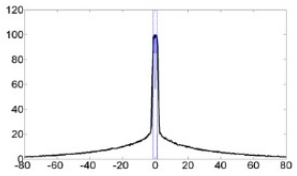
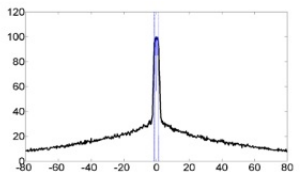
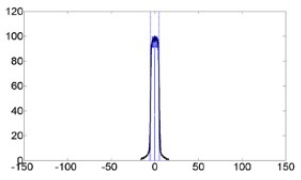
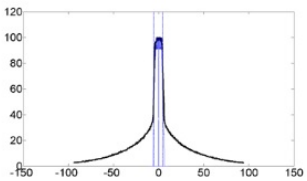
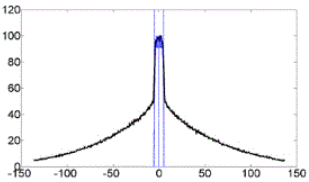
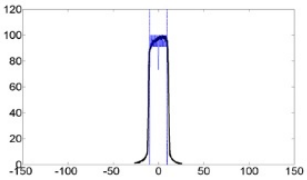
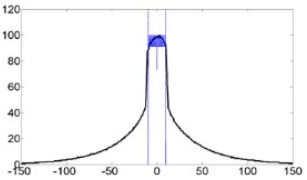
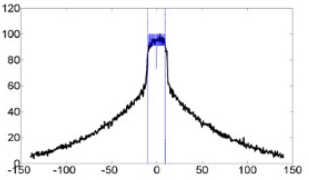
IEC 60601-2-44: 2012 203.110

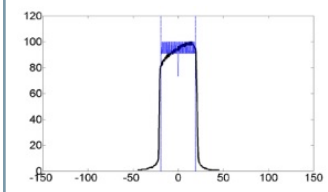
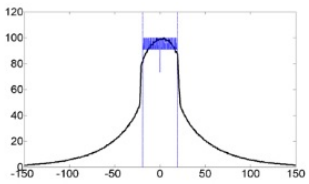
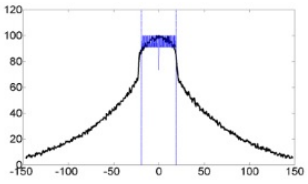
Dose profiles for single axial scans have been measured for the narrowest, a midrange and the widest collimation. For each of these collimations, the dose profiles have been measured in the center of the Ø 16 cm CTDI phantom (head) and in the center of the Ø 32 cm CTDI phantom (body).

The phantoms were centered in the isocenter and aligned with the scanner axes. For the measurements, a semiconductor diode sensor has been moved through the phantom. Each profile is represented as percentage of the maximum value.

In the diagrams below dose profiles (thick lines) are presented as a percentage of their maximum value. Sensitivity profiles for the detector slices used in these collimations are plotted as thin lines. The dotted lines indicate the nominal collimation.

Dose profiles:

	no phantom	phantom 16 cm	phantom 32 cm
4 × 0.6 mm			
2 × 5 mm			
32 × 0.6 mm			

	no phantom	phantom 16 cm	phantom 32 cm
64 × 0.6 mm			
x-Axis: z-position [mm] y-Axis: rel. dose & ssp[%]			

Full Width at Half Maximum (FWHM) of dose profiles:

Collimation	No phantom	Ø 16 cm phantom	Ø 32 cm phantom	Tolerance*
4 × 0.6 mm	3.80 mm	4.01 mm	4.41 mm	± 1.5 mm
2 × 5 mm	10.14 mm	11.10 mm	12.51 mm	± 4.0 mm
32 × 0.6 mm	22.42 mm	24.19 mm	45.97 mm	± 4.0 mm
32 x 1.2 mm	41.97 mm	44.39 mm	79.02 mm	± 4.0 mm
*) The stated tolerances are determined by the accuracy of the measurement method.				

For acceptance testing dose profile widths are measured using film (GAFCHROMIC XR-QA) and without any phantom. The tube is fixed and positioned at 12 o'clock. The exposure parameters are chosen to overexpose the film (130 kV, 160 mA, 6 s, twice). Using this method no densitometry is needed to evaluate the film. The width of the blackened range is a measure for the base width of the profile. Nominal values and tolerances are defined.

Dose profile widths measured using film:

Collimation	Nominal blackening width	Tolerance
4 × 0.6 mm	5.2 mm	± 1.0 mm
2 × 5 mm	12.4 mm	± 1.5 mm
32 × 0.6 mm	24.7 mm	± 2.0 mm
32 x 1.2 mm	44.2 mm	± 2.0 mm

2.1.14 Beam quality, leakage technique factors and minimum filtration

According to:

21 CFR 1020.30 (h)(2)(i)

21 CFR 1020.30 (h)(4)(ii)

21 CFR 1020.30 (m)

IEC 60601-2-44: 2002, 29.201.5

IEC 60601-2-44: 2012, 203.7.1

IEC 60601-2-44: 2012, 203.7.3

Beam quality expressed as first Half Value Layer (HVL):

Tube voltage	Half Value Layer (HVL)	
80 kV	≥ 4.5 mm Al	(typical 5.3 mm)
110 kV	≥ 5.0 mm Al	(typical 7.1 mm)
130 kV	≥ 5.0 mm Al	(typical 8.1 mm)

Leakage technique factors:

≤ 0.8 mGy/h	1 m distance to focal spot with 130 kV, 3500 W

Minimum filtration:

CARE filter tube	Equivalent to 5.5 mm Al at 140 kV
CARE filter beam limiting device	0.5 mm Al

2.1.15 Stray radiation

According to:

IEC 60601-2-44: 2002, 29.208.101

IEC 60601-2-44: 2012, 203.13.2

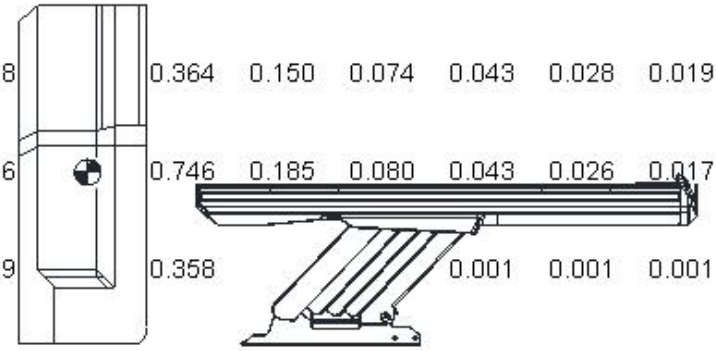
Stray radiation is indicated for the horizontal and vertical planes on the basis of the scanner coordinate system (intersection of scanner axis with scan plane) at maximum tube voltage (130 kV) and maximum total collimation width (38.4 mm).

A cylindrical PMMA phantom with a diameter of 32 cm and a length of 15 cm is centered in the scan plane for the stray radiation measurement. A 1000 cm^3 spherical dose chamber with 140mm diameter is used for the measurement.

The accuracy of stated value is determined by the accuracy of chamber positioning (±5 cm in each direction, which may lead to tolerances up to ±20%) and by the accuracy of the dosemeter (±5% or 0.004µGy/mAs, whichever is greater). Backscatter from cabin walls or similar surface may cause additional variation in the radiation measurement.

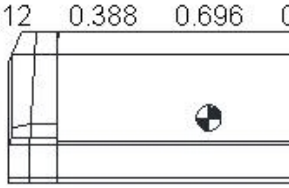
Stray radiation in microGray (µGy) per mAs:

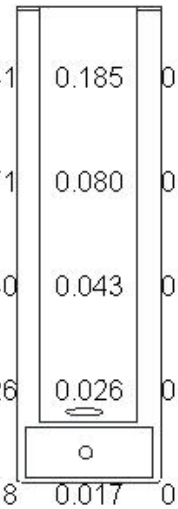
	2.0m	1.5m	1.0m	0.5m	0m	0.5m	1.0m	1.5m	2.0m	2.5m	3.0m	3.5m
1.5m	0.030	0.040	0.025	0.004	0.004	0.011	0.055	0.044	0.032	0.023	0.017	0.013
1.0m	0.036	0.056	0.088	0.019	0.004	0.076	0.094	0.059	0.038	0.026	0.019	0.014
0.5m	0.042	0.071	0.139	0.348		0.364	0.150	0.074	0.043	0.028	0.019	0.014
0m	0.043	0.075	0.172	0.696		0.746	0.185	0.080	0.043	0.026	0.017	0.016
0.5m	0.039	0.067	0.129	0.329		0.358			0.001	0.001	0.001	0.001



Stray radiation (vertical)

	1.5m	1.0m	0.5m	0m	0.5m	1.0m	1.5m
2.0m	0.030	0.036	0.041	0.043	0.041	0.037	0.030
1.5m	0.041	0.059	0.071	0.075	0.071	0.057	0.042
1.0m	0.029	0.093	0.144	0.172	0.141	0.093	0.031
0.5m	0.003	0.012	0.388	0.696	0.359	0.022	0.003
0m	0.003						0.002
0.5m	0.010	0.085	0.363	0.746	0.389	0.087	0.013
1.0m	0.052	0.095	0.141	0.185	0.146	0.098	0.057
1.5m	0.041	0.054	0.071	0.080	0.070	0.057	0.043
2.0m	0.029	0.034	0.040	0.043	0.041	0.035	0.029
2.5m	0.020	0.023	0.026	0.026	0.026	0.023	0.021
3.0m	0.015	0.016	0.018	0.017	0.018	0.017	0.015
3.5m	0.011	0.012	0.013	0.016	0.013	0.012	0.012





Stray radiation (horizontal)

2.1.16 Performance specification of automatic exposure controls

According to:

IEC 60601-2-44: 2012, 203.106

The CT scanner offers different types of automatic exposure controls for adaptation of the exposure to the individual patient.

- CARE Dose 4D: mAs adaptation to patient size, longitudinal, and angular tube current modulation
- ECG-Pulsing: Adaptation of tube current to the patient's ECG signal

The modulation type applied depends on the protocol selected and the individual setting:

Modulation types for automatic exposure controls:

Protocol types, organ characteristics	Modulation type	
Abdomen AngioBody Pediatric Head Pediatric Angio Head Neck Pelvis Shoulder Spine Thorax	XYZ exposure control (CARE Dose 4D)	The tube current is adapted to the patient size. It is varied along the z-axis according to the patient's attenuation profile and modulated angularily according to the patient's angular attenuation profile that has been measured online.
Adult Head Adult Angio Head	Z exposure control (CARE Dose 4D)	The tube current is adapted to the patient size and varied along the z-axis according to the patient's attenuation profile.
Body-Perfusion Extremities	XY exposure control (CARE Dose)	The tube current is modulated angularily according to the patient's angular attenuation profile that has been measured online and is based on the user-selected mAs.
Osteo	Fixed exposure control (CARE Dose 4D)	The tube current is adapted to an average patient size and kept constant.
Cardio Respiratory (Z exposure control for chest pain protocols only)	ECG-Pulsing Combined with fixed exposure control (CARE Dose4D)	The tube current is adapted to an average patient size and pulsed according to the patient's ECG signal.

CARE Dose/CARE Dose 4D

CARE Dose 4D automatically adapts the tube current to the patient's body size and shape.

Using the patient's topogram, CARE Dose4D evaluates two profiles of the patient's X-ray attenuation in the a.p. and lateral directions.

Based on these profiles, the mAs value is adapted to the patient during the subsequent CT scans. The adaption follows an adaptation curve, which determines the correlation between X-ray attenuation and tube current. The adaptation curve has been derived from the clinical optimization for constant diagnostic image quality.

The adaptation curve is based on three parameters:

- A reference X-ray attenuation, related to a typical adult patient size of approximately 70-80 kg, are internally stored in the CT system for the considered organ characteristics and depending on the selected protocol.

Reference attenuation values for the Automatic Exposure Control:

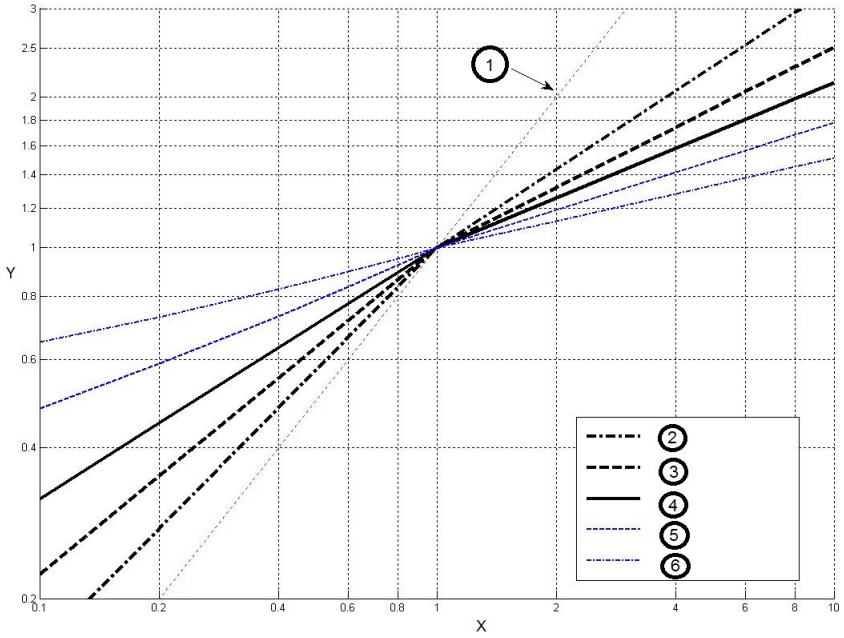
Organ characteristic	Reference X-ray attenuation
Head, Angio Head	50

Organ characteristic	Reference X-ray attenuation
Neck	100
Shoulder	1200
Thorax, Respiratory	600
Cardio	400
Abdomen, Angio Body, Body Perfusion	1000
Pelvis, Osteo	1500
Spine	800
Extremities	500

- A reference mAs value “ref. mAs” (or “ref. mAs/rot”), which is adjustable by the operator on the Scan Card to modify the overall dose and image quality of the scan range.
- An adjustment of the adaptation strength, which can be selected in five steps (very weak, weak, average, strong, very strong), is provided to configure the adaption for body sizes smaller or larger than the reference body.

The curve below shows the theoretical adaptation curve for a cylindrical body shape. Depending on the individual patient geometry, the curve may deviate from this theoretical function. Moreover, the curve may be cut depending on the system’s power limit.

Depending on the modulation type of the protocol, the patient size adapted tube current can be fixed, modulated along the z-axis according to the adaption curve, modulated according to the patient’s online measured angular attenuation profile (CARE Dose), or combination of these.



Adaption of mAs to patient attenuation with adjustable strengths

x Patient attenuation relative to reference attenuation

y mAs relative to ref. mAs

(1) contrast noise

(2) very strong

(3) strong

(4) average

(5) weak

(6) very weak

Guidance on the Use of Radiation Shields to Reduce Patient Dose in CT scanning

In general the effects of radiation shields used in CT examinations on patient dose and image quality depend on several factors, in particular the material and shape of the radiation shield, its placement and the patient's body shape. Since these factors vary with each individual examination setup, a generalized and scientifically validated statement is not feasible.

However, the following statements may provide a better understanding of the situation.

- **Radiation shield positioned outside of the directly exposed range of a CT scan and the corresponding topogram scan:**

  No negative influence on image quality and patient dose, therefore, no concerns in using radiation shields in this situation.

- **Radiation shield positioned within the directly exposed range of a CT scan or the corresponding topogram scan:**

  Shielding may affect image quality and patient dose.

  - Image reconstruction algorithms widely suppress artifacts caused by metals in or on the patient's body but artifacts cannot generally be excluded.
  - Siemens' automatic exposure control, CARE Dose 4D, can be substantially affected by the patient's body. To minimize a potential negative effect of Radiation Shields it is recommended to scan the Topogram without shields and use the shields only during the subsequent CT examination.
  - While patient dose is reduced in areas protected by the radiation shield, consequently the image noise may increase (in addition to the presence of artifacts) and affect diagnosis.
  - An alternative to shielding that also only locally reduces the radiation dose in the patient is a dedicated scan mode like X-CARE that is offered on most of the CT systems manufactured by Siemens Healthcare.

In summary, the use of radiation shields positioned within the directly exposed range of a CT scan cannot generally be recommended. Patient dose and image quality must be taken into consideration.

ECG Gating

The tube current is synchronized to the patient's ECG signal and gated depending on the user defined setting for the image time window, which is set as a percentage range of the RR interval (e.g. 70% to 70%). Outside the tube current gating window the tube current is reduced to 20% of the value inside the gating window.

2.2 Image quality

2.2.1 Low-contrast detectability

Low contrast detectability has been measured in a body mode at 130 kV with the following parameter settings: 10 mm slice, kernel B20s, FoV 150 mm with a 20 cm Catphan consisting of a plastic disc with rod inserts of different size and contrast. The phantom is positioned approximately 2 cm of the plane to avoid the ring suppression algorithm to diminishing the contrast of the concentrically positioned inserts.

The low contrast detectability is determined by the visual inspection of the images. The specified low contrast is the smallest diameter that can be visualized for a certain contrast at the specified dose.

This method is subjective and depends on the viewer's visual acuity and on statistical fluctuations of the image noise. Therefore, the stated diameter combines the evaluation of several human observers and several images with same scan parameters.

Due to the high variability of these results it is difficult to objectively measure low contrast detectability. Hence, this visual method is not recommended for an Acceptance Test.

$CTDI_{vol}$ (32 cm) for low-contrast detectability of 5 mm / 3 HU in 20 cm Catphan for 10 mm slice:

	CTDIvol (32 cm)	Collimation
Sequence	8.86 mGy	1 × 10.0 mm

2.2.2 CT number

According to:

IEC 60601-2-44: 2012, 203.6.7.2

The CT number is specified for air (-1000 ± 4 HU) and water (0 ± 4 HU) only. The specification is not valid for other materials in the beam. The CT number for water is valid for a cylindrical phantom with a diameter ranging from 20 cm to 30 cm, and that is centered, and aligned with the scanner axis.

The CT-numbers for other materials depend on the kV settings.

2.2.3 Uniformity

According to:

IEC 60601-2-44: 2012, 203.6.7.2

The uniformity of the CT values is specified for a typical scan mode within a cylindrical 20 cm water phantom that has been centered in the scan plane without any other objects in the scan field.

Nominal MTF values of a wire place in plastics:

Cross-field uniformity (maximum)	≤ 4 HU	Typical mode, 20 cm water phantom
Cross-field uniformity (typical)	≤ 2 HU	Typical mode, 20 cm water phantom

2.2.4 Image noise

According to:

21 CFR 1020.33 (c)(3)(i), (c)(3)(v)

IEC 60601-2-44: 2009, 203.6.7.2

IEC 60601-2-44: 2012, 203.6.7.2

A circular Region of Interest (ROI) with a diameter of approximately 40% of the phantom diameter was used to measure the noise in images of a 20 cm and 30 cm water phantom using the typical head and typical body conditions of operation.

Image noise:

	Ø 20 cm water phantom	Ø 30 cm water phantom
Typical adult head	3.16 HU ± 10%	-
Typical adult body	4.71 HU ± 10%	11.86 HU ± 10%

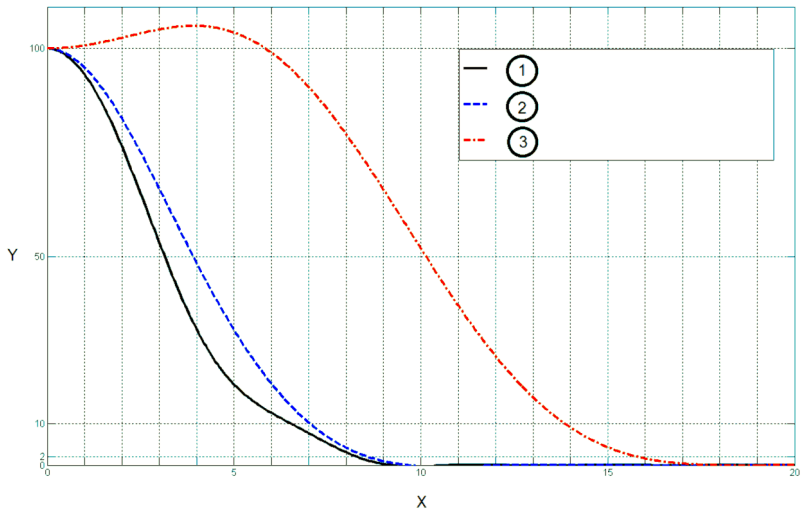
2.2.5 High-Contrast-Resolution, Modulation Transfer Function (MTF)

According to:

21 CFR 1020.33 (c)(3)(ii), (c)(3)(v)

IEC 60601-2-44: 2012, 203.6.7.2

The Point Spread Function (PSF) image is obtained by scanning a 0.1 mm tungsten wire placed in plastic. The two-dimensional Fourier transformation of the PSF generates a Modulation Transfer Function (MTF) of the system.



Measured MTF of an image of a wire placed in plastics

x Spatial frequency [LP/cm]

y MTF [%]

(1) Typical Head (H31s)

(2) Typical Body (B41s)

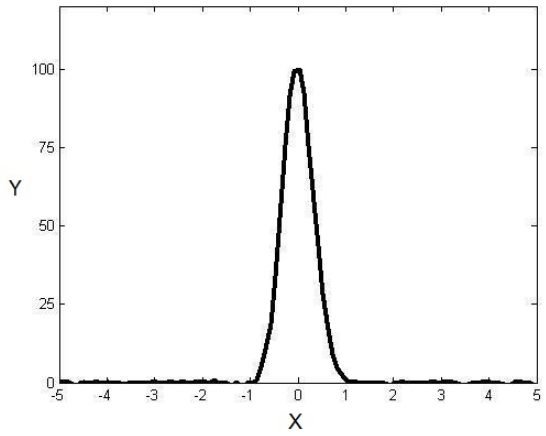
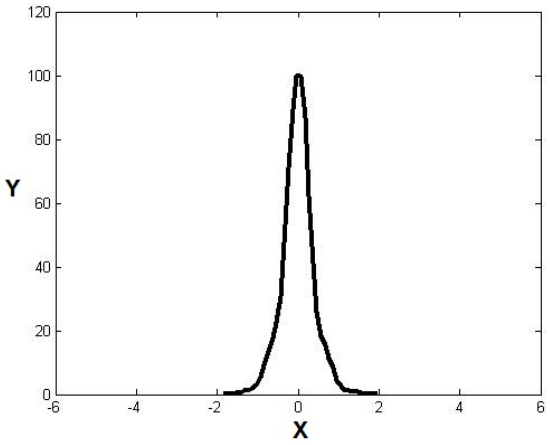
(3) Sharpest (U90s)

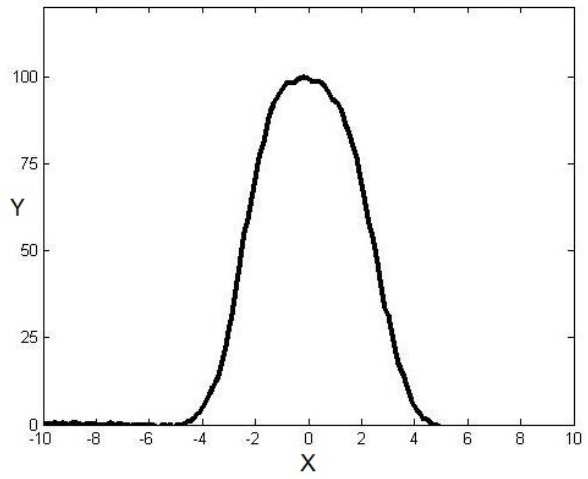
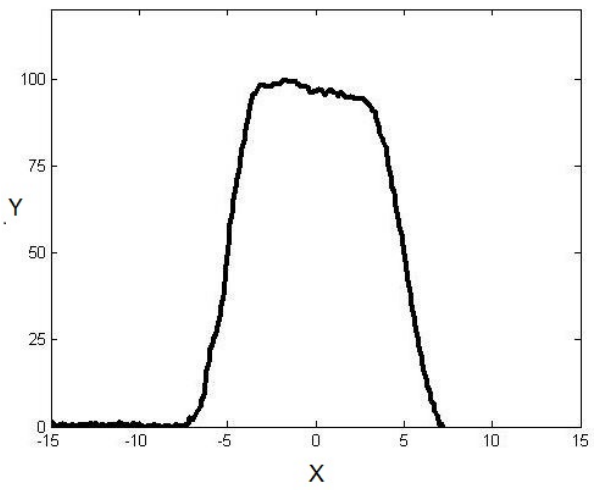
Low contrast detectability:

MTF	Typical Head (H31s)	Typical Body (B41s)	Sharpest (U90s)
50%	3.08 LP/cm ± 10%	3.85 LP/cm ± 10%	10.09 LP/cm ± 10%
10%	6.50 LP/cm ± 10%	7.02 LP/cm ± 10%	13.80 LP/cm ± 10%
2%	8.31 LP/cm ± 10%	8.56 LP/cm ± 10%	15.82 LP/cm ± 10%

2.2.6 Sensitivity profiles

Slice sensitivity profiles (SSP) were measured on the basis of images of a thin air slit that was moved through the scan plane along the z-axis in very small steps and imaged after each scan in a single axial scan. The sensitivity profile is the profile of relative HU values measured along the z-direction at the location of the air slit in the image. Sensitivity profiles are valid for head mode and body mode.

Thinnest axial slice	
	
x: z [mm] y: SSP [%]	x: z [mm] y: SSP [%]
Normial slice thickness 0.6 mm (with 0.6 mm slice thickness license)	**Normial slice thickness 0.75 mm (without 0.6 mm slice thickness license)**

Midrange axial slice	Maximum axial slice
	
x: z [mm] y: SSP [%]	x: z [mm] y: SSP [%]
Normial slice thickness 5 mm	Normial slice thickness 10 mm

2.2.7 Nominal tomographic section thicknesses

According to:

21 CFR 1020.33 (c)(3)(iii)

IEC 60601-2-44: 2009, 203.6.7.2

IEC 60601-2-44: 2012, 203.6.7.2

Nominal tomographic section thicknesses:

Application	Mode	Acquisition (mm)	Reconstructable Slice Width (mm)																		
			0.6*	0.75	1.0	1.2	1.5	2.0	2.4	3.0	4.0	4.8	5.0	6.0	7.0	7.2	8.0	9.6	10	15	20
Routine	Spiral	32 × 0.6, 12 × 0.6, 4 × 0.6	x	x	x		x	x		x	x		x	x	x		x		x		
		32 × 1.2					x	x		x	x		x	x	x		x		x		
	Sequence	32 × 1.2						x		x	x		x	x	x		x		x		
		32 × 0.6			x		x	x		x	x		x	x	x		x		x		
		12 × 0.6			x		x	x		x	x		x								
		4 × 0.6		x	x		x	x													
Thorax HR Seq	Sequence	2 × 1			x			x													
		1 × 2						x													

* Not applied for system without 0.6 mm slice thickness license

a) For Multi-scan only

b) For Respiratory only

c) For CAREVision only

d) Preset for CareVision 32 x 0.6 mm acquisition, not configurable

e) Depending on scan protocol selections, not all combinations shown are selectable

Application	Mode	Acquisition (mm)	Reconstructable Slice Width (mm)																	
			0.6*	0.75	1.0	1.2	1.5	2.0	2.4	3.0	4.0	4.8	5.0	6.0	7.0	7.2	8.0	9.6	10	15	20
Cardio Respiratory	Spiral	32 × 0.6	x	x	x		x	x		x	x		x								
		32 × 1.2					x	x		x	x		x								
	Sequence	32 × 1.2						x		x	x		x	x[b]	x[b]		x[b]		x[b]		
		32 × 0.6			x		x	x		x	x		x	x[b]	x[b]		x[b]		x[b]		
		12 × 0.6[b]			x		x	x		x	x		x								
		4 × 0.6		x	x		x	x													
CAREVision Biopsy	Sequence	1 × 10																	x		
		32 × 0.6										x[d]				x		x[c]			
		12 × 0.6							x												
		1 × 2						x													
Perfusion	Spiral	32 × 0.6, 12 × 0.6, 4 × 0.6	x	x	x		x	x		x	x		x	x	x		x		x		
		32 x 1.2					x	x		x	x		x	x	x		x		x		
	Multiscan or Sequence[e]	32 × 1.2						x		x	x		x	x	x		x		x	x[a]	x[a]
		32 × 0.6			x		x	x		x	x		x	x	x		x		x	x[a]	
		12 × 0.6			x		x	x		x	x		x								
		4 × 0.6		x	x	x	x	x	x												
		1 × 10																	x		
		2 × 5											x						x		
		1 × 2						x													
		2 × 1			x			x													
TestBolus	Sequence	1 × 10																	x		
		2 × 5											x						x		
		1 × 2						x													
		2 × 1			x			x													
		4 × 0.6	x			x			x												

* Not applied for system without 0.6 mm slice thickness license

a) For Multi-scan only

b) For Respiratory only

c) For CAREVision only

d) Preset for CareVision 32 x 0.6 mm acquisition, not configurable

e) Depending on scan protocol selections, not all combinations shown are selectable

According to:

21 CFR 1020.33 (c)(3)(v)

Tolerances of slice thickness:

0.6 mm	Tolerance: ± 0.3 mm
0.75 mm	Tolerance: ± 0.5 mm
1 - 2 mm	Tolerance: ± 50 %
> 2 mm	Tolerance: ± 1.0 mm

3 Dosimetry and imaging performance report (32-slice and 16-slice)

This chapter provides dose and imaging performance data. The data is in accordance with the US code of federal regulations 21 CFR 1020.33 (c) and the standard of the International Electrotechnical Commission IEC 60601-2-44.

This chapter provides the following information:

- $CTDI_{100}$ for typical CT conditions of operation with regard to typical head, body, cardiac, head perfusion and pediatric body modes
- Dose factors showing the relative changes of $CTDI_{100}$ compared to the $CTDI_{100}$ of each typical mode in varying a scan parameter
- Dosimetry data, such as beam quality, dose profiles, and stray radiation tables
- Image noise and High-Contrast-Resolution (HCR) of the typical modes
- Homogeneity of CT values and low-contrast resolution
- Reconstructable slice thicknesses

3.1 Dose information

3.1.1 General information about dose indication

The CT system provides information about the $CTDI_{vol}$ and Dose Length Product (DLP) as defined by the IEC 60601-2-44 standard. Both values are displayed on the user interface of the scanner before and after each scan range. In addition, these values are stored in the Patient Protocol and the DICOM Structured Dose Report. The $CTDI_{vol}$ represents the average energy dose (expressed as Air KERMA) within a cylindrical PMMA phantom and is aligned with the scanner axis and centered in the scan plane. The phantom diameter to which the displayed $CTDI_{vol}$ refers depends on the default application of the used protocol.

In general, the values of the body region “Body” are also used for the body region “Neck” .

Child protocols are recommended for pediatric patients under the age of 12 years and with a normal body size. For child protocols, factors for conversion of the displayed $CTDI_{vol}$ and DLP for the 32 cm phantom to equivalent $CTDI_{vol}$ and DLP for the 16 cm phantom are stated.

The CTDI values given in this manual are valid for deactivated CARE Dose 4D , as the feature is not adapted to phantom measurements.

Further information regarding dose reduction functions is provided in the *syngo CT Instructions for use*.

3.1.2 Phantoms and methods

According to:

21 CFR 1020.33 (c)(3)(v)

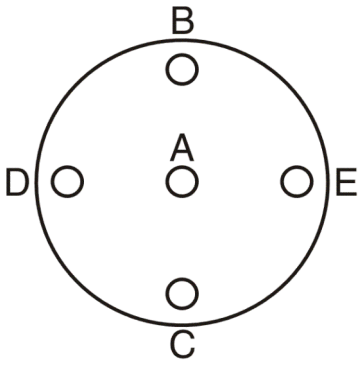
IEC 60601-2-44 (Ed. 3.1) 203.108

This chapter describes both phantoms and methods used to establish the dose values reported below. It also describes how to measure and determine $CTDI_{vol}$, in order to verify against the value displayed at the scanner.

The phantoms used to measure the CTDI values are circular cylinders of PMMA of diameter 16 cm (for head applications) or 32 cm (for body applications), and with a length of at least 14 cm. They contain holes parallel to the axis of the phantom (A – E) to hold 100 mm dose chambers.

Phantoms are aligned with the scanner axis and centered in the scan field. A dose chamber with an active length of 100 mm has been used for the dose measurements. All dose values are given in Air KERMA.

$CTDI_{100}$ is measured in the center (A) and peripheral drillings at 3 o'clock, 6 o'clock, 9 o'clock and 12 o'clock positions (B – E).



$CTDI_{100}$ locations in dosimetry phantoms with the line of sight towards the front side of the gantry

To ensure correct dose measurements, it is recommended to use a dosimeter conforming to IEC 61674. The dosimeter needs to be calibrated with beam qualities suitable for the CT energy spectrum examined, for example, CT beam qualities "RQT" according to IEC 61267.

The dose is measured in single axial scans, which enables the dose chamber to measure the integrated dose profile along the z-direction over 10 cm, centered to the scan plane. The magnitude of the measured values should lay above the accuracy of the dosimeter. Therefore, it may be necessary to select a reasonably large tube current and exposure time or to average the dosimeter readings over several scans. For measurements with the dose chamber in one of the peripheral positions of the phantom, averaging over several scans is highly recommended, otherwise the measured values may be distorted by the position of the scan start angle.

IEC 61674: 2012

'Medical electrical equipment – Dosimeters with ionization chambers and/or semiconductor detectors as used in X-ray diagnostic imaging'

IEC 61267: 2005

'Radiation conditions for use in the determination of characteristics'

To calculate the $CTDI_{100}$ from the dosimeter readings (usually displayed as dose integrated over z-direction, i.e., as Length-Dose-Product (DLP), for example in mGy·cm³) the value has to be divided by the nominal beam collimation. The nominal beam collimation is equal to the acquisition displayed at the scanner's console (for example. Acquisition 32 × 0.6 mm = 1.92 cm).

$$CTDI_{100} = \frac{1}{N \times T} \cdot \int_{-50\,mm}^{+50\,mm} D(z)\ dz = \frac{LDP}{NxT}$$

LDP – measured Length-Dose-Product [mGy·cm]

Note that the reading may also be displayed as dose averaged over the chamber length, e.g. in mGy.

NxT – Nominal Beam Collimation [cm]

This is valid for all nominal beam collimations ≤ 4 cm.

The $CTDI_w$ is the sum of a third of the $CTDI_{100}$ measured in the phantom's central chamber position ($CTDI_{100}^c$) and two thirds of the average of $CTDI_{100}$ measured in the phantom's four peripheral chamber position ($CTDI_{100}^p$).

$$CTDI_w = {}^1/_3 \cdot CTDI_{100}^c + {}^2/_3 \cdot \overline{CTDI_{100}^p}$$

According to it's definition, $CTDI_w$ needs to be derived from $CTDI_{100}$ measured in single axial scans. In this situation the $CTDI_{vol}$ is equal to the $CTDI_w$.

In general, the $CTDI_{vol}$ displayed is derived from the $CTDI_w$ by multiplication with a factor that takes into account the table feed during scanning:

For spiral scanning	$CTDI_{vol} = \frac{CTDI_w}{p}$
For axial scanning	$CTDI_{vol} = CTDI_w \cdot \frac{NxT}{v_f}$
For axial scanning without table feed	$CTDI_{vol} = n \cdot CTDI_w$
CT_p – Pitch factor **NxT – Nominal collimation** **v_f – Table feed per scan**	

3.1.3 Typical CT conditions of operation

According to:

21 CFR 1020.33

IEC 60601-2-44: 2002, 29.1.102.1

IEC 60601-2-44: 2012, 203.109.1

The following table provides scan parameter settings for typical modes of operation according to the default setting of the Siemens scan protocols (with deactivated CARE Dose 4D).

Typical CT conditions of operation:

Application type	Typical Head	Typical Body	Typical Cardiac	Typical Head Perfusion	Typical Pediatric Body
Patient type		Adult	Adult		Child
Scan type	Sequence	Spiral	Quickscan	Multiscan	Spiral
Protocol name	HeadSeq	Abdomen Routine	CaScoreSeq	NeuroPCT	Abdomen Routine
Tube voltage	130 kV	130 kV	130 kV	80 kV	110 kV
Tube current time product	230 mAs	120 eff. mAs	30 mAs/rot	150 mAs	98 eff. mAs
Tube current	115 mA	120 mA	74 mA	150 mA	245 mA
Rotation time	1 s	0.6 s	0.48 s	1 s	0.6 s
Number of scans	14	1	8	1	1
Scan time	2 s	11.6 s	0.41 s	40 s	5.37 s
Scan length	124.8 mm	200 mm	134.7 mm	0 mm	200 mm
Pitch factor or table feed	9.6 mm	0.6	17.2 mm	0	1.5
Collimation	16 × 0.6 mm	16 × 1.2 mm	16 x 1.2 mm	16 × 1.2 mm	16 × 1.2 mm
Data acquisition	16 × 0.6 mm	16 × 1.2 mm	16 x 1.2 mm	16 × 1.2 mm	16 × 1.2 mm
Total collimation	9.6 mm	19.2 mm	19.2 mm	19.2 mm	19.2 mm
Reconstructed slice width	5 mm	5 mm	3 mm	10 mm	5 mm
Kernel	H31s	B41s	B35s	H31s	B41s

3.1.4 $CTDI_{100}$ value for typical CT conditions of operation

According to:

21 CFR 1020.33 (c)(2)(i)

IEC 60601-2-44: 2002, 29.1.102.1(a)

IEC 60601-2-44: 2012, 203.109.1(a)

The following table indicates the CTDI values for typical modes specified in (→ Page 8 *Phantoms and methods*).

There is no significant difference in the exposure of the peripheral chamber positions. The stated dose chamber positions are B - E according to their positions in the phantom (up, down, left, and right). See (→ Page 8 *Phantoms and methods*)

$CTDI_{100}$ values of the typical CT conditions of operation:

Application type	Typical Head	Typical Body	Typical Cardiac	Typical Head Perfusion	Typical Pediatric Body
Patient size		Adult	Adult		Child
CTDI phantom	Ø 16 cm	Ø 32 cm	Ø 32 cm	Ø 16 cm	Ø 32 cm
$CTDI_{100}$ (mGy)	per scan	per rotation	per scan	per scan	per rotation

Application type	Typical Head	Typical Body	Typical Cardiac	Typical Head Perfusion	Typical Pediatric Body
Patient size		Adult	Adult		Child
Chamber position A (central)	53.2	4.7	2.0	354.4	6.2
Chamber position B (Up)	56.3	9.0	3.8	397.2	12.5
Chamber position C (down)	57.4	8.9	3.7	402.2	12.4
Chamber position D (left)	55.5	8.9	3.7	389.4	12.3
Chamber position E (right)	55.5	9.0	3.8	387.7	12.4
Average peripheral	56.2	9.0	3.7	394.1	12.4
$CTDI_w$	55.2	7.5	3.1	380.9	10.3
$CTDI_{vol}$	55.2	12.6	3.5	380.9	6.9

3.1.5 Dose factors related to the $CTDI_{100}$ for typical CT conditions of operation

According to:

21 CFR 1020.33 (c)(2)(ii)

21 CFR 1020.33 (c)(2)(iii)

IEC 60601-2-44: 2002, 29.1.102.1(b), (c)

IEC 60601-2-44: 2012, 203.109.1(b), (c)

The system provides one permanent shaped X-ray beam filter as default settings for all applications, so the $CTDI_{100}$ is influenced by the following selectable scan parameters:

- kV
- Acquisition
- mAs values (mAs, eff. mAs, mAs/rot)

The $CTDI_{100}$ is not influenced by the rotation time or recon parameters, such as Kernel or FoV.

In the following tables, the $CTDI_{100}$ for the typical mode is represented by the value 1.00, shown in bold. $CTDI_{100}$ for varying scan parameters are given as a proportion of the $CTDI_{100}$ for the typical mode.

Dose factors related to the $CTDI_{100}$ for varying tube voltage:

Tube voltage		Typical Head	Typical Body	Typical Cardiac	Typical Head Perfusion	Typical Pediatric Body
		CTDI Phantom Ø 16 cm	CTDI Phantom Ø 32 cm	CTDI Phantom Ø 32 cm	CTDI Phantom Ø 16 cm	CTDI Phantom Ø 32cm
80 kV	Central	0.28	0.22	0.22	**1.00**	0.35
	Peripheral	0.30	0.27	0.27	**1.00**	0.40
	Weighted	0.29	0.26	0.26	**1.00**	0.39
110 kV	Central	0.69	0.65	0.65	2.45	**1.00**
	Peripheral	0.69	0.68	0.68	2.35	**1.00**
	Weighted	0.69	0.67	0.67	2.38	**1.00**
130 kV	Central	**1.00**	**1.00**	**1.00**	3.57	1.55
	Peripheral	**1.00**	**1.00**	**1.00**	3.39	1.48
	Weighted	**1.00**	**1.00**	**1.00**	3.45	1.49

Dose factors related to the $CTDI_{100}$ for varying acquisition type:

Acquisition	Typical Head	Typical Body	Typical Cardiac	Typical Head Perfusion	Typical Pediatric Body
2 × 1 mm	1.40	1.53	1.53	1.52	1.52
4 × 0.6 mm	1.17	1.27	1.27	1.27	1.27
12 × 0.6 mm	1.14	1.24	1.24	1.25	1.25
16 × 0.6 mm	**1.00**	1.10	1.10	1.10	1.10
2 × 5 mm	0.82	0.90	0.90	0.90	0.90
12 × 1.2 mm	0.89	0.98	0.98	0.98	0.98
16 × 1.2 mm	0.91	**1.00**	**1.00**	**1.00**	**1.00**

Dose factors related to the $CTDI_{100}$ for varying mAs:

Dose factors are valid for deactivated CARE Dose4D.

Current	Typical Head		Typical Body		Typical Cardiac		Typical Head Perfusion		Typical Pediatric Body	
	mAs	factor	eff. mAs	factor	mAs	factor	mAs/rot	factor	eff. mAs	factor
25 mA	50	0.22	25	0.21	10	0.34	25	0.17	10	0.10
74 mA	148	0.64	74	0.61	30	**1.00**	74	0.49	30	0.30
115 mA	230	**1.00**	115	0.96	47	1.56	115	0.77	46	0.47
120 mA	240	1.04	120	**1.00**	49	1.63	120	0.80	48	0.49
150 mA	300	1.30	150	1.25	61	2.03	150	**1.00**	60	0.61
245 mA	490	2.13	245	2.04	100	3.32	245	1.63	98	**1.00**
345 mA	690	3.00	345	2.88	140	4.68	345	2.30	138	1.41

3.1.6 Dose levels causing deterministic radiation effects

According to:

IEC 60601-1-3: 2008, 5.2.4.5+Annex A.2

IEC 60601-2-44: 2012, 203.5.2.4.5

Certain modes of operation allow selections of scan parameters that may lead to an accumulated peripheral $CTDI_{100}$ of more than 1 Gy. This dose may exceed the threshold for deterministic radiation effects on the patient's skin or eye lenses (see IEC 60601-1-3:2008, Annex A.2, 5.2.4.5).

The accumulated peripheral $CTDI_{100}$ may serve as a rough estimation of skin or eye lens dose. However other factors may influence the dose to cause deterministic radiation effects, for example:

- A deviation of the patient's body diameter from the standard CTDI phantom size may lead to a patient's skin dose that is noticeably higher than indicated by the accumulated peripheral $CTDI_{100}$. Such a deviation may occur, for example, if a body perfusion examination is performed with a very thin patient.
- Using the scan protocol dedicate to body scans to perform head scan (for which the dose estimation should be based on Φ16 cm), may lead to a patient skin dose that is great higher than common estimation.
- Repeating examinations within a short time period (compared to the biological recovery time for deterministic radiation effects) may lead to deterministic radiation damages, even if the accumulated peripheral $CTDI_{100}$ of the single examinations was below 1 Gy.

In general, the accumulated peripheral $CTDI_{100}$ can be derived from the displayed $CTDI_{vol}$ by multiplying the $CTDI_{vol}$ with a given factor that depends on tube voltage.

Ratio of peripheral $CTDI_{100}$ to displayed $CTDI_{vol}$:

Tube voltage	Typical Head Ø 16 cm	Typical Body Ø 32 cm
80 kV	1.0	1.2
110 kV	1.0	1.2
130 kV	1.0	1.2

By using the default Siemens scan protocols for patients with a standard patient size, without changing the default settings of the scan parameters, and without repeating the scans, the accumulated peripheral $CTDI_{100}$ will be kept reasonably below 1 Gy.

The following list gives examples of situations that may lead to an accumulated peripheral $CTDI_{100}$ of 1.0 Gy and above (numbers are approximations). The list refers to default Siemens scan protocols and concentrates on scan modes with relatively high radiation exposure. This list is not exhaustive.

- Use of perfusion protocols with changes in kV, scan times, or mAs, for example:
  - *Neuro PCT* with tube voltage changed from 80 kV to 130 kV (≈1.3 Gy)
  - *Neuro PCT* with scan time increased from 40 s to ≈ 102 s
  - *Neuro PCT* with mAs increased from 150 mAs to ≈ 381 mAs
- Scanning of sequence protocols without table feed, for example:
  - Approximately 18 scans of *Head Neuro Seq* without table feed
- Repeating standard sequences or spiral scans within an examination, for example:
  - Repeating application of the default protocol *Head Neuro Seq* (approximately 18 times)
  - Repeating application of the default protocol *Abdomen Routine* (approximately 67 times)
- Use of Care Vision protocol (without Hand CARE) for Head intervention*
  - By applying 130 kV/130 mA for scan time ≈ 27 s
  - Make 15s scan with 130 kV by applying mAs ≈ 232 mAs

*) The case may happen according to above hint.

To prevent unintended, excessive exposure, the CT system provides tools for Dose Notification and Dose Alert. The default threshold value for Dose Alert is an accumulated $CTDI_{vol}$ of 1.0 Gy.**

**) In case of applying body scan protocols for thin patients, small children or head examinations, the actual exposure dose may be underestimated. Special calculation need to be applied to prevent excessive exposure even the displayed accumulated $CTDI_{vol}$ is still below 1.0 Gy threshold.

3.1.7 Overview of $CTDI_{100}$ values (mGy/100mAs)

Phantom: Ø 16 cm Application: Routine head								
Voltage	Collimation [mm]	2 x 1	4 x 0.6	12 x 0.6	16 x 0.6	2 x 5	12 x 1.2	16 x 1.2
	Total [mm]	2.0	2.4	7.2	9.6	10.0	14.4	19.2
80 KV	$CTDI_{100}$, central	8.97	7.48	7.38	6.49	5.31	5.75	5.88
	$CTDI_{100}$, peripheral	9.96	8.30	8.20	7.21	5.90	6.39	6.54
	CTDIw	9.63	8.03	7.92	6.97	5.71	6.17	6.32
110 KV	$CTDI_{100}$, central	22.14	18.45	18.07	15.93	13.01	14.10	14.42
	$CTDI_{100}$, peripheral	23.56	19.63	19.31	16.94	13.90	15.04	15.39
	CTDIw	23.09	19.24	18.90	16.60	13.61	14.73	15.07
130 KV	$CTDI_{100}$, central	32.44	27.04	26.37	23.15	18.99	20.57	21.02
	$CTDI_{100}$, peripheral	34.15	28.46	27.77	24.43	19.99	21.69	22.18
	CTDIw	33.58	27.98	27.30	24.00	19.66	21.32	21.79

Phantom: Ø 32 cm Application: Adult body, Pediatric body*								
Voltage	Collimation [mm]	2 x 1	4 x 0.6	12 x 0.6	16 x 0.6	2 x 5	12 x 1.2	16 x 1.2
	Total [mm]	2.0	2.4	7.2	9.6	10.0	14.4	19.2
80 KV	$CTDI_{100}$, central	2.22	1.85	1.83	1.61	1.32	1.43	1.46
	$CTDI_{100}$, peripheral	5.08	4.24	4.23	3.71	3.04	3.30	3.37
	CTDIw	4.13	3.44	3.43	3.01	2.47	2.67	2.73
110 KV	$CTDI_{100}$, central	6.47	5.39	5.28	4.64	3.80	4.12	4.22
	$CTDI_{100}$, peripheral	12.80	10.67	10.53	9.23	7.59	8.24	8.43
	CTDIw	10.69	8.91	8.78	7.70	6.32	6.87	7.03
130 KV	$CTDI_{100}$, central	10.05	8.38	8.18	7.19	5.89	6.38	6.52
	$CTDI_{100}$, peripheral	19.00	15.83	15.45	13.70	11.13	12.18	12.46
	CTDIw	16.01	13.35	13.03	11.53	9.38	10.25	10.48
*) See Conversion factor for CTDIvol from phantom Ø 32 cm to phantom Ø 16 cm								

No phantom Free air								
Voltage	Collimation [mm]	2 x 1	4 x 0.6	12 x 0.6	16 x 0.6	2 x 5	12 x 1.2	16 x 1.2
	Total [mm]	2.0	2.4	7.2	9.6	10.0	14.4	19.2
80 KV		16.61	13.84	13.55	11.90	9.75	10.56	10.82
110 KV		35.07	29.22	28.44	25.03	20.48	22.19	22.71
130 KV		49.20	41.00	39.78	35.08	28.64	31.15	31.86

3.1.8 Tolerances for CTDI

According to:

21 CFR 1020.33

IEC 60601-2-44: 2002, 29.1.102.1(d)

IEC 60601-2-44: 2002, 50.101

IEC 60601-2-44: 2012, 203.109.1(d)

IEC 60601-2-44: 2012, 201.12.1.101

IEC 60601-2-44: 2012, Amd.1 203.112

The actual exposure values, such as $CTDI_{100}$, $CTDI_{w}$, $CTDI_{vol}$ and DLP, may deviate from the values displayed at the scanner and from the values stated in this manual.

Tolerances for CTDI values:

	Typical deviation	Max. tolerance
80 kV	within ± 15%	± 40%
110 kV, 130 kV	within ± 15%	± 30%

The linearity of the radiation output (linearity of measured dose related to displayed mAs) is ± 10%.

3.1.9 Conversion factor for $CTDI_{vol}$ for pediatric protocols from Ø 32 cm phantom to Ø 16 cm phantom

The displayed and reported $CTDI_{vol}$ and DLP refers to cylindrical PMMA phantoms of a diameter of 16 cm for head application and of a diameter of 32 cm for body applications (adult and pediatric protocols), according to IEC 60601-2-44.

Since a child's body diameter may typically be better represented by a 16 cm phantom than by a 32 cm phantom, factors for the conversion of $CTDI_{vol}$ and DLP from a phantom size of 32 cm to a phantom size of 16 cm are given in the following table.

Conversion factor for $CTDI_{vol}$:

kV setting	Conversion factor from Ø 32 cm to Ø 16 cm
80 kV	2.3
110 kV	2.1
130 kV	2.1

For a typical pediatric body protocol at 110 kV, the displayed $CTDI_{vol}$ and DLP (related to the Ø 32 cm CTDI-phantom) are 6.89 mGy and 167.24 mGy × cm. For the same protocol, the $CTDI_{vol}$ and DLP of a Ø 16 cm CTDI-phantom are 2.1 times higher than the values of a Ø 32 cm CTDI-phantom, resulting in $CTDI_{vol}$ as 14.47 mGy and DLP as 351.20 mGy × cm.

3.1.10 $CTDI_{vol}$ for topograms

The $CTDI_{vol}$vol for topogram scans may be estimated according to IEC 60601-2-44, Annex B.

Since the collimation (4 × 0.6 mm) and table speed (100 mm/s) for the topogram is fixed, the $CTDI_{vol}$ for topograms is stated in the following table depending on the kV and mA values.

$CTDI_{vol}$ for topograms:

Protocol type	Head	Body
Phantom size	Ø 16 cm	Ø 32 cm
	$CTDI_{vol}$ µGy/mA	$CTDI_{vol}$ µGy/mA
80 kV	1.9	0.8
110 kV	4.6	2.1
130 kV	6.7	3.2

3.1.11 $CTDI_{free\ air}$

According to:

IEC 60601-2-44: 2012, 203.109.2

The $CTDI_{free\ air}$ is stated in the following table based on the typical body mode (shown in bold type) for varying collimation, and kV. Additionally, the $CTDI_{free\ air}$ for the typical head mode is stated.

$CTDI_{free\ air}$ for based on typical body mode(mGy):

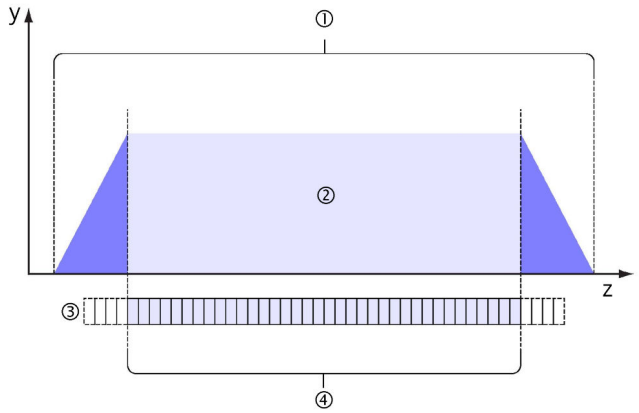
Acquisition [mm]	Variation of the collimation						
	2 × 1	4 × 0.6	12 × 0.6	16 × 0.6	2 × 5	12 × 1.2	16 × 1.2
Total collimation [mm]	2.0	2.4	7.2	9.6	10	14.4	19.2
80 kV	19.93	16.61	16.26	14.28	11.70	12.68	12.99
110 kV	42.08	35.07	34.13	30.03	24.58	26.62	27.25
130 kV	59.04	49.20	47.73	42.10	34.37	37.38	**38.23**

$CTDI_{free\ air}$ for typical head mode(mGy):

Collimation [mm]	16 × 0.6
Total [mm]	9.6
130 kV	**80.69**

3.1.12 Geometric efficiency in the z-direction

The dose efficiency is defined by IEC 60601-2-44 as the integral of the “free in air” in the isocenter along the z-axis over the acquisition range in the z-direction, expressed as percentage of the total integral of the dose profile in the z-direction. The acquisition range is the distance spanned by the selected detector elements along the z-axis. The displayed $CTDI_{vol}$ and DLP reflect the dose efficiency of a collimation according to the definition of $CTDI_{vol}$.



Correlation of dose profile and collimation regarding dose efficiency

y Dose

z z-axis

(1) Total dose profile width

(2) Dose profile

(3) Detector

(4) Acquisition range

Dose efficiencies for the various collimations:

Acquisition (mm)	Total collimation (mm)	Dose efficiency
16 x 1.2	19.2	88%
12 x 1.2	14.4	90%
16 x 0.6	9.6	80%
12 x 0.6	7.2	71%
2 × 5 mm	10.0	100%
1 × 10mm	10.0	100%
4 × 0.6 mm	2.4	70%
2 × 1 mm	2.0	70%
1 × 2 mm	2.0	70%

3.1.13 Dose profiles

According to:

21 CFR 1020.33 (c)(2)(iv)

21 CFR 1020.33 (c)(3)(iv)

21 CFR 1020.33 (c)(3)(v)

IEC 60601-2-44: 2002, 29.1.103.1

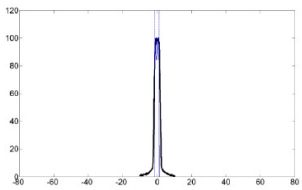
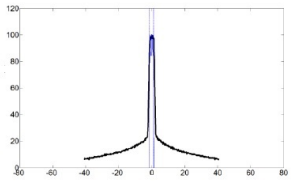
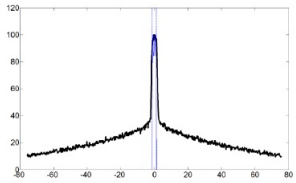
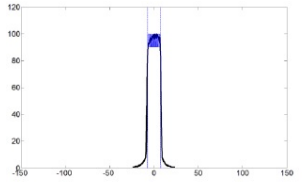
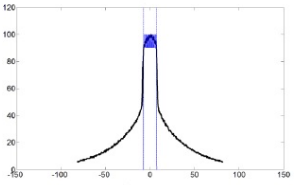
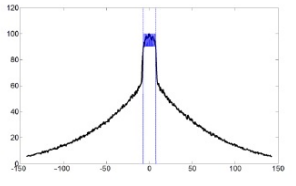
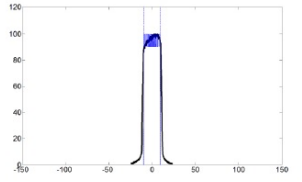
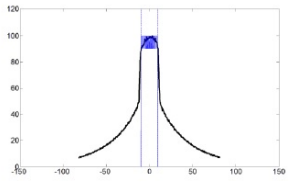
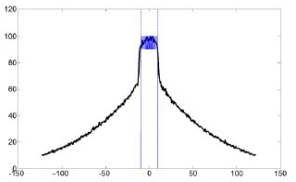
IEC 60601-2-44: 2012, 203.110

Dose profiles for single axial scans have been measured for the narrowest, a midrange and the widest collimation. For each of these collimations, the dose profiles have been measured in the center of the Ø 16 cm CTDI phantom (head) and in the center of the Ø 32 cm CTDI phantom (body).

The phantoms were centered in the isocenter and aligned with the scanner axes. For the measurements, a semiconductor diode sensor has been moved through the phantom. Each profile is represented as percentage of the maximum value.

In the diagrams below dose profiles (thick lines) are presented as a percentage of their maximum value. Sensitivity profiles for the detector slices used in these collimations are plotted as thin lines. The dotted lines indicate the nominal collimation.

Dose profiles:

	no phantom	phantom 16 cm	phantom 32 cm
4 × 0.6 mm			
12 × 1.2 mm			
16 × 1.2 mm			

Full Width at Half Maximum (FWHM) of dose profiles:

Collimation	No phantom	Ø 16 cm phantom	Ø 32 cm phantom	Tolerance
4 × 0.6 mm	3.67 mm	3.90 mm	4.27 mm	± 1.5 mm

Collimation	No phantom	Ø 16 cm phantom	Ø 32 cm phantom	Tolerance
12 x1.2mm	16.09 mm	17.79 mm	44.83 mm	± 4.0 mm
16 x1.2mm	22.09 mm	24.28 mm	58.56 mm	± 4.0 mm

The stated tolerances are determined by the accuracy of the measurement method.

For acceptance testing dose profile widths are measured using film (GAFCHROMIC XR-QA) and without any phantom. The tube is fixed and positioned at 12 o'clock. The exposure parameters are chosen to overexpose the film (130 kV, 160 mA, 6 s, twice). Using this method no densitometry is needed to evaluate the film. The width of the blackened range is a measure for the base width of the profile. Nominal values and tolerances are defined.

Norminal values and tolerances for dose profile measured by blackened range with film:

Collimation	Nominal blackening width	Tolerance
4 x 0.6 mm	4.6 mm	± 1.0 mm
12 x1.2 mm	18.0 mm	± 1.5 mm
16 x1.2 mm	23.7 mm	± 1.5 mm

3.1.14 Beam quality, leakage technique factors and minimum filtration

According to:

21 CFR 1020.30 (h)(2)(i)

21 CFR 1020.30 (h)(4)(ii)

21 CFR 1020.30 (m)

IEC 60601-2-44: 2002, 29.201.5

IEC 60601-2-44: 2012, 203.7.1

IEC 60601-2-44: 2012, 203.7.3

Beam quality expressed as first Half Value Layer (HVL):

Tube voltage	Half Value Layer (HVL)	
80 kV	≥ 4.5 mm Al	(typical 5.2 mm)
110 kV	≥ 5.0 mm Al	(typical 6.9 mm)
130 kV	≥ 5.0 mm Al	(typical 7.9 mm)

Leakage technique factors:

≤ 0.8 mGy/h	1 m distance to focal spot with 140 kV, 3500 W

Minimum filtration:

CARE filter tube	Equivalent to 5.5 mm Al at 140 kV
CARE filter beam limiting device	0.5 mm Al

3.1.15 Stray radiation

According to:

IEC 60601-2-44: 2002, 29.208.101

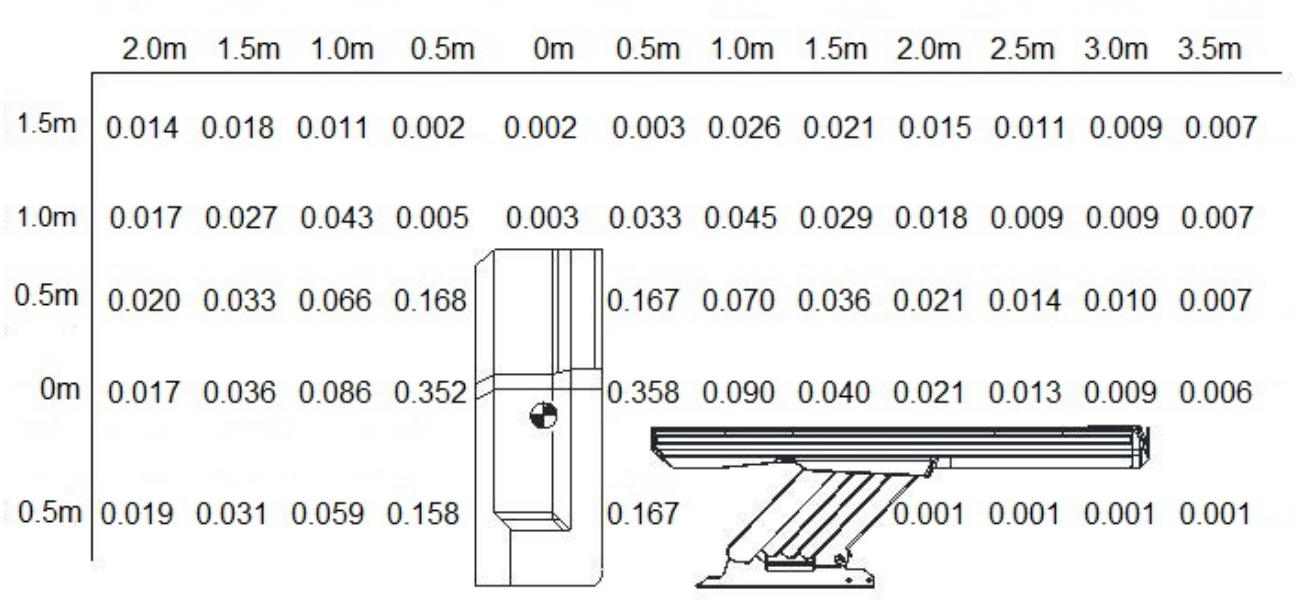
IEC 60601-2-44: 2012, 203.13.2

Stray radiation is indicated for the horizontal and vertical planes on the basis of the scanner coordinate system (intersection of scanner axis with scan plane) at maximum tube voltage (130 kV) and maximum total collimation width (19.6 mm).

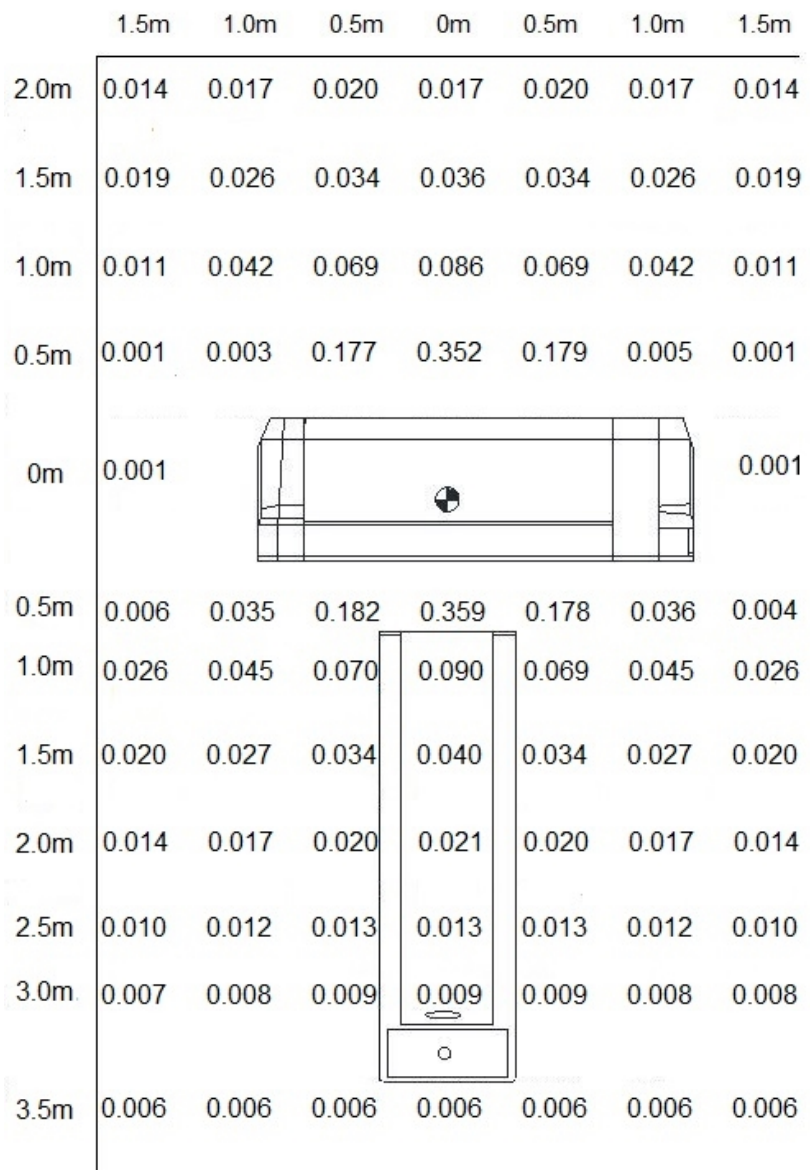
A cylindrical PMMA phantom with a diameter of 32 cm and a length of 15 cm is centered in the scan plane for the stray radiation measurement. A 1000 cm^3 spherical dose chamber with 140mm diameter is used for the measurement.

The accuracy of stated value is determined by the accuracy of chamber positioning (±5 cm in each direction, which may lead to tolerances up to ±20%) and by the accuracy of the dosemeter (±5% or 0.004µGy/mAs, whichever is greater). Backscatter from cabin walls or similar surface may cause additional variation in the radiation measurement.

Stray radiation in microGray (µGy) per mAs:



Stray radiation (vertical)



Stray radiation (horizontal)

3.1.16 Performance specification of automatic exposure controls

According to:

IEC 60601-2-44: 2012, 203.106

The CT scanner offers different types of automatic exposure controls for adaptation of the exposure to the individual patient.

- CARE Dose 4D: mAs adaptation to patient size, longitudinal, and angular tube current modulation
- ECG-Pulsing: Adaptation of tube current to the patient's ECG signal

The modulation type applied depends on the protocol selected and the individual setting:

Modulation types for automatic exposure controls:

Protocol types, organ characteristics	Modulation type	
Abdomen AngioBody Pediatric Head Pediatric Angio Head Neck Pelvis Shoulder Spine Thorax	XYZ exposure control (CARE Dose 4D)	The tube current is adapted to the patient size. It is varied along the z-axis according to the patient's attenuation profile and modulated angularly according to the patient's angular attenuation profile that has been measured online.
Adult Head Adult Angio Head	Z exposure control (CARE Dose 4D)	The tube current is adapted to the patient size and varied along the z-axis according to the patient's attenuation profile.
Body-Perfusion Extremities	XY exposure control (CARE Dose)	The tube current is modulated angularly according to the patient's angular attenuation profile that has been measured online and is based on the user-selected mAs.
Osteo	Fixed exposure control (CARE Dose 4D)	The tube current is adapted to an average patient size and kept constant.
Cardio Respiratory (Z exposure control for chest pain protocols only)	ECG-Pulsing Combined with fixed exposure control (CARE Dose4D)	The tube current is adapted to an average patient size and pulsed according to the patient's ECG signal.

CARE Dose/CARE Dose 4D

CARE Dose 4D automatically adapts the tube current to the patient's body size and shape.

Using the patient's topogram, CARE Dose4D evaluates two profiles of the patient's X-ray attenuation in the a.p. and lateral directions.

Based on these profiles, the mAs value is adapted to the patient during the subsequent CT scans. The adaption follows an adaptation curve, which determines the correlation between X-ray attenuation and tube current. The adaptation curve has been derived from the clinical optimization for constant diagnostic image quality.

The adaptation curve is based on three parameters:

- A reference X-ray attenuation, related to a typical adult patient size of approximately 70-80 kg, are internally stored in the CT system for the considered organ characteristics and depending on the selected protocol.

Reference attenuation values for the Automatic Exposure Control:

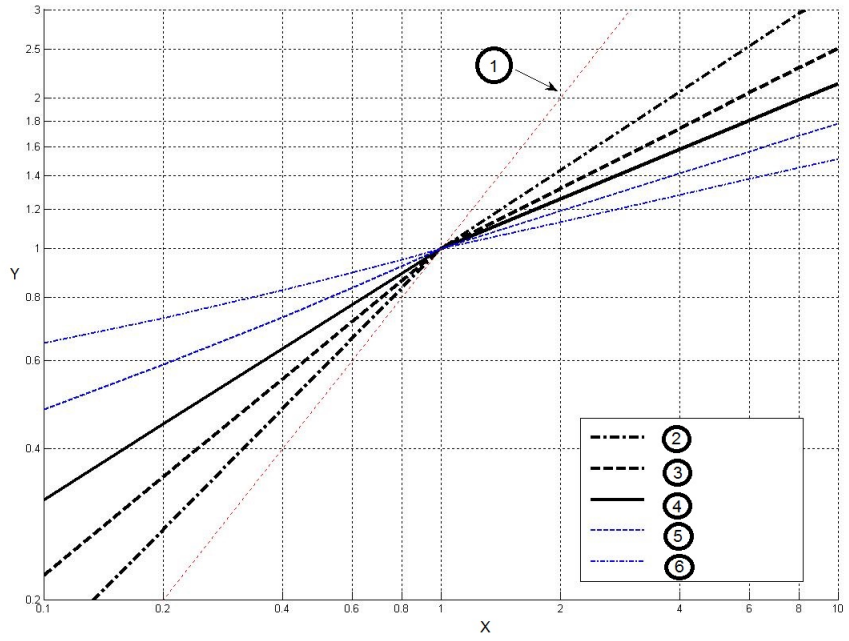
Organ characteristic	Reference X-ray attenuation
Head, Angio Head	50
Neck	100
Shoulder	1200
Thorax, Respiratory	600
Cardio	400

Organ characteristic	Reference X-ray attenuation
Abdomen, Angio Body, Body Perfusion	1000
Pelvis, Osteo	1500
Spine	800
Extremities	500

- A reference mAs value “ref. mAs” (or “ref. mAs/rot”), which is adjustable by the operator on the Scan Card to modify the overall dose and image quality of the scan range.
- An adjustment of the adaptation strength, which can be selected in five steps (very weak, weak, average, strong, very strong), is provided to configure the adaption for body sizes smaller or larger than the reference body.

The curve below shows the theoretical adaptation curve for a cylindrical body shape. Depending on the individual patient geometry, the curve may deviate from this theoretical function. Moreover, the curve may be cut depending on the system’s power limit.

Depending on the modulation type of the protocol, the patient size adapted tube current can be fixed, modulated along the z-axis according to the adaption curve, modulated according to the patient’s online measured angular attenuation profile (CARE Dose), or combination of these.



Adaption of mAs to patient attenuation with adjustable strengths

x Patient attenuation relative to reference attenuation

y mAs relative to ref. mAs

(1) contrast noise

(2) very strong

(3) strong

(4) average

(5) weak

(6) very weak

Guidance on the Use of Radiation Shields to Reduce Patient Dose in CT scanning

In general the effects of radiation shields used in CT examinations on patient dose and image quality depend on several factors, in particular the material and shape of the radiation shield, its placement and the patient's body shape. Since these factors vary with each individual examination setup, a generalized and scientifically validated statement is not feasible.

However, the following statements may provide a better understanding of the situation.

- **Radiation shield positioned outside of the directly exposed range of a CT scan and the corresponding topogram scan:**

  No negative influence on image quality and patient dose, therefore, no concerns in using radiation shields in this situation.

- **Radiation shield positioned within the directly exposed range of a CT scan or the corresponding topogram scan:**

  Shielding may affect image quality and patient dose.

  - Image reconstruction algorithms widely suppress artifacts caused by metals in or on the patient's body but artifacts cannot generally be excluded.
  - Siemens' automatic exposure control, CARE Dose 4D, can be substantially affected by the patient's body. To minimize a potential negative effect of Radiation Shields it is recommended to scan the Topogram without shields and use the shields only during the subsequent CT examination.
  - While patient dose is reduced in areas protected by the radiation shield, consequently the image noise may increase (in addition to the presence of artifacts) and affect diagnosis.
  - An alternative to shielding that also only locally reduces the radiation dose in the patient is a dedicated scan mode like X-CARE that is offered on most of the CT systems manufactured by Siemens Healthcare.

In summary, the use of radiation shields positioned within the directly exposed range of a CT scan cannot generally be recommended. Patient dose and image quality must be taken into consideration.

ECG Gating

The tube current is synchronized to the patient's ECG signal and gated depending on the user defined setting for the image time window, which is set as a percentage range of the RR interval (e.g. 70% to 70%). Outside the tube current gating window the tube current is reduced to 20% of the value inside the gating window.

3.2 Image quality

3.2.1 Low-contrast detectability

Low contrast detectability has been measured in a body mode at 130 kV with the following parameter settings: 10 mm slice, kernel B20s, FoV 150 mm with a 20 cm Catphan consisting of a plastic disc with rod inserts of different size and contrast. The phantom is positioned approximately 2 cm of the plane to avoid the ring suppression algorithm to diminishing the contrast of the concentrically positioned inserts.

The low contrast detectability is determined by the visual inspection of the images. The specified low contrast is the smallest diameter that can be visualized for a certain contrast at the specified dose.

This method is subjective and depends on the viewer's visual acuity and on statistical fluctuations of the image noise. Therefore, the stated diameter combines the evaluation of several human observers and several images with same scan parameters.

Due to the high variability of these results it is difficult to objectively measure low contrast detectability. Hence, this visual method is not recommended for an Acceptance Test.

$CTDI_{vol}$ (32 cm) for low-contrast detectability of 5 mm / 3 HU in 20 cm Catphan for 10 mm slice:

	CTDIvol (32 cm)	Collimation
Sequence	12.00 mGy	1 × 10.0 mm

3.2.2 CT number

According to:

IEC 60601-2-44: 2012, 203.6.7.2

The CT number is specified for air (-1000 ± 4 HU) and water (0 ± 4 HU) only. The specification is not valid for other materials in the beam. The CT number for water is valid for a cylindrical phantom with a diameter ranging from 20 cm to 30 cm, and that is centered, and aligned with the scanner axis.

The CT-numbers for other materials depend on the kV settings.

3.2.3 Uniformity

According to:

IEC 60601-2-44: 2012, 203.6.7.2

The uniformity of the CT values is specified for a typical scan mode within a cylindrical 20 cm water phantom that has been centered in the scan plane without any other objects in the scan field.

Nominal MTF values of a wire place in plastics:

Cross-field uniformity (maximum)	≤ 4 HU	Typical mode, 20 cm water phantom
Cross-field uniformity (typical)	≤ 2 HU	Typical mode, 20 cm water phantom

3.2.4 Image noise

According to:

21 CFR 1020.33 (c)(3)(i), (c)(3)(v)

IEC 60601-2-44: 2012, 203.6.7.2

A circular Region of Interest (ROI) with a diameter of approximately 40% of the phantom diameter was used to measure the noise in images of a 20 cm and 30 cm water phantom using the typical head and typical body conditions of operation.

Image noise:

	Ø 20 cm water phantom	Ø 30 cm water phantom
Typical head	2.91 HU ± 10%	-
Typical adult body	4.56 HU ± 10%	11.60 HU ± 10%

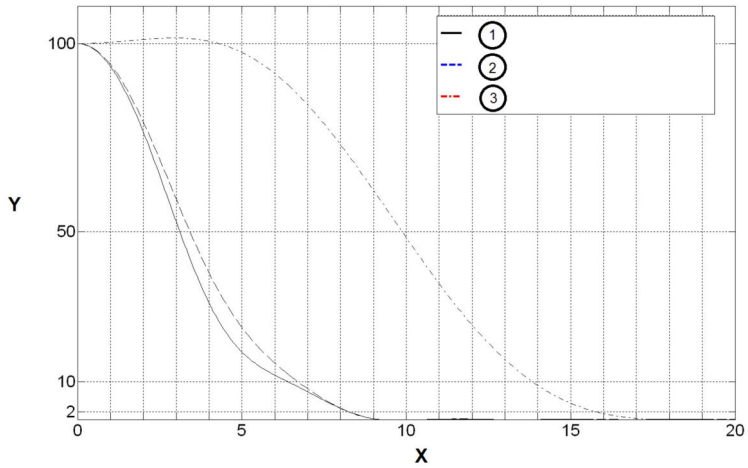
3.2.5 High-Contrast-Resolution, Modulation Transfer Function (MTF)

According to:

21 CFR 1020.33 (c)(3)(ii), (c)(3)(v)

IEC 60601-2-44: 2012, 203.6.7.2

The Point Spread Function (PSF) image is obtained by scanning a 0.1 mm tungsten wire placed in plastic. The two-dimensional Fourier transformation of the PSF generates a Modulation Transfer Function (MTF) of the system.



Measured MTF of an image of a wire placed in plastics

x Spatial frequency (LP/cm)

y MTF (%)

(1) Typical Head (H31s)

(2) Typical Body (B41s)

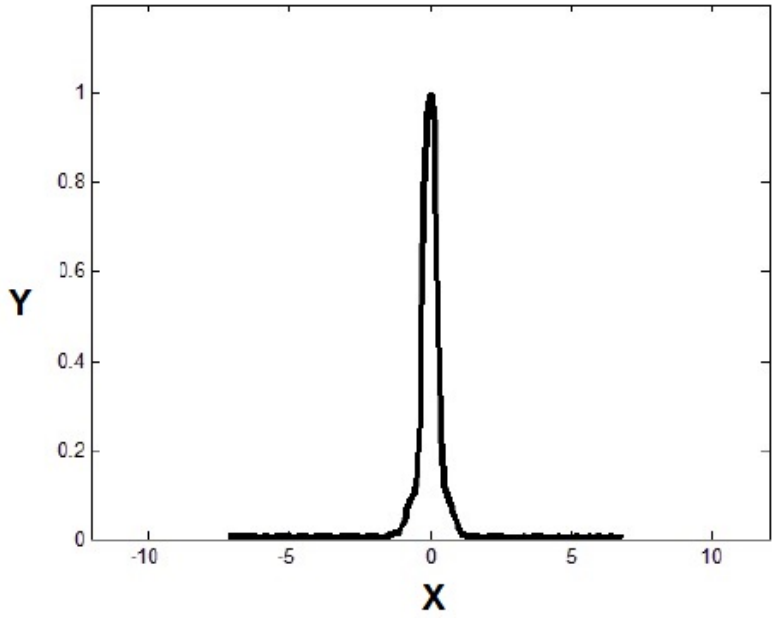
(3) Sharpest (U90s)

Nominal MTF values for a wire placed in plastic:

MTF	Typical Head (H31s)	Typical Body (B41s)	Sharpest (U90s)
50%	3.00 LP/cm ± 10%	3.73 LP/cm ± 10%	9.75 LP/cm ± 10%
10%	6.30 LP/cm ± 10%	7.00 LP/cm ± 10%	13.80 LP/cm ± 10%
2%	8.25 LP/cm ± 10%	8.40 LP/cm ± 10%	15.78 LP/cm ± 10%

3.2.6 Sensitivity profiles

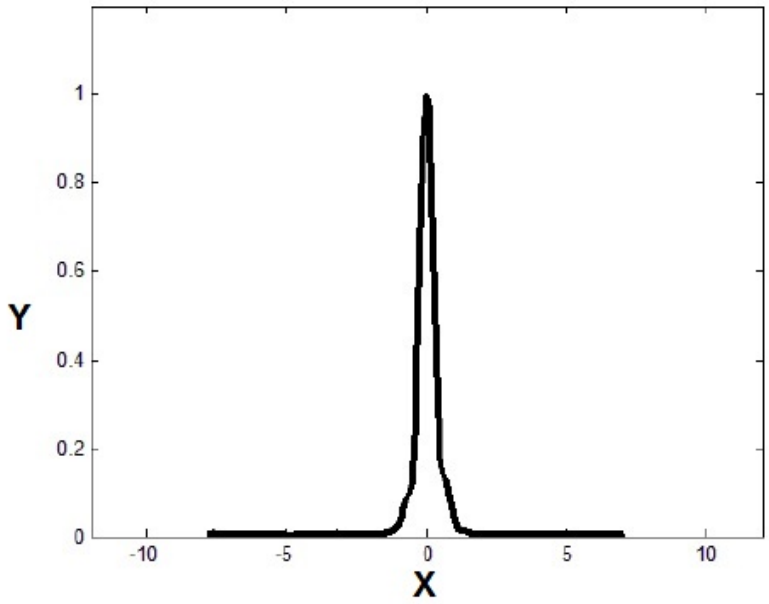
Slice sensitivity profiles (SSP) were measured on the basis of images of a thin air slit that was moved through the scan plane along the z-axis in very small steps and imaged after each scan in a single axial scan. The sensitivity profile is the profile of relative HU values measured along the z-direction at the location of the air slit in the image. Sensitivity profiles are valid for head mode and body mode.



Thinnest axial slice 0.6 mm

x z [mm]

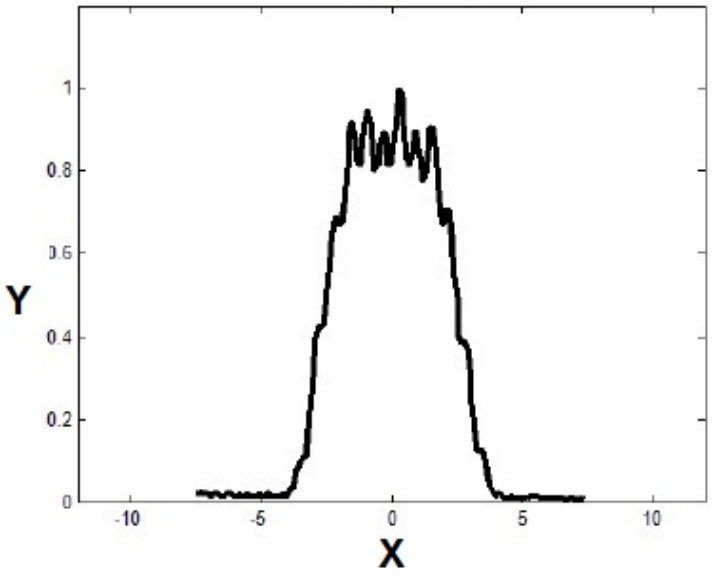
y SSP [%]



Thinnest axial slice 0.75 mm

x z [mm]

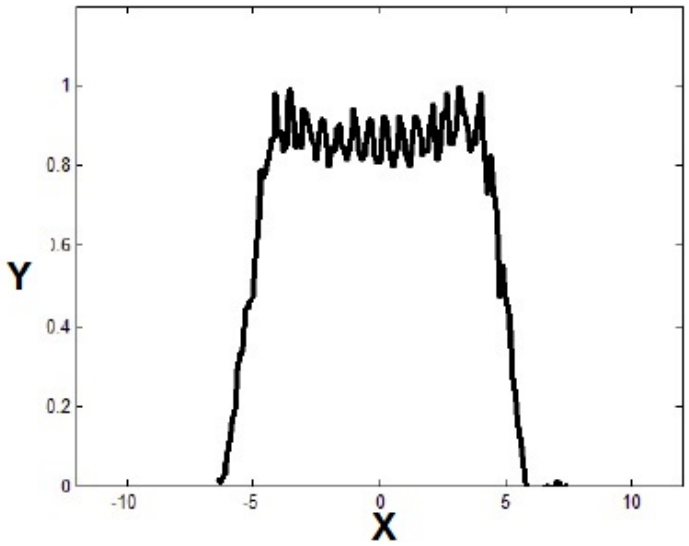
y SSP [%]



Midrange axial slice 5 mm

x z [mm]

y SSP [%]



Maximum axial slice 10 mm

x z [mm]

y SSP [%]

3.2.7 Nominal tomographic section thicknesses

According to:

21 CFR 1020.33 (c)(3)(iii)

IEC 60601-2-44: 2012, 203.6.7.2

Nominal tomographic section thicknesses:

Application	Mode	Acquisition (mm)	Reconstructable Slice Width (mm)																
			0.6[a]	0.75	1.0	1.2	1.5	2.0	2.4	3.0	4.0	4.8	5.0	6.0	7.0	7.2	8.0	9.6	10	15
Routine	Spiral	16 × 0.6, 12 × 0.6, 4 × 0.6	x	x	x		x	x		x	x		x	x	x		x		x	
		12 × 1.2, 16 × 1.2					x	x		x	x		x	x	x		x		x	
	Sequence	12 × 1.2, 16 × 1.2						x		x	x		x	x	x		x		x	
		16 × 0.6	x		x		x	x		x	x		x	x	x		x		x	
		12 × 0.6			x		x	x		x	x		x							
		4 × 0.6		x	x		x	x												
Thorax HR Seq	Sequence	2 × 1			x			x												
		1 × 2						x												

a) Not applied for system without 0.6 mm slice thickness license

b) For Respiratory only

c) For CAREVision only

d) Depending on scan protocol selections, not all combinations shown are selectable

e) For Multiscan only

Application	Mode	Acquisition (mm)	Reconstructable Slice Width (mm)																
			0.6[a]	0.75	1.0	1.2	1.5	2.0	2.4	3.0	4.0	4.8	5.0	6.0	7.0	7.2	8.0	9.6	10	15
Cardio Respiratory	Spiral	16 × 0.6		x	x		x	x		x	x		x							
		16 × 1.2					x	x		x	x		x							
	Sequence	12 × 1.2 [b], 16 × 1.2					x	x		x	x		x	x[b]	x[b]		x [b]		x [b]	
		16 × 0.6			x		x	x		x	x		x	x[b]	x[b]		x [b]			
		12 × 0.6 [b]			x		x	x		x	x		x							
		4 × 0.6		x	x		x	x												
CAREVision Biopsy	Sequence	16 × 1.2[c]										x				x		x		
		1 × 10																	x	
		16 × 0.6										x								
		12 × 0.6							x											
		1 × 2						x												
Perfusion	Multiscan or Sequence[d]	16 × 1.2						x		x	x		x	x	x		x		x	x[e]
		12 × 1.2						x		x	x		x	x	x		x		x	
		16 × 0.6		x	x		x	x		x	x		x	x	x		x			
		12 × 0.6		x	x		x	x		x	x		x							
		4 × 0.6		x	x	x	x	x	x											
		1 × 10																	x	
		2 × 5											x						x	
		1 × 2						x												
		2 × 1			x			x												
TestBolus	Sequence	1 × 10																	x	
		2 × 5											x						x	
		1 × 2						x												
		2 × 1			x			x												
		4 × 0.6	x			x			x											

a) Not applied for system without 0.6 mm slice thickness license

b) For Respiratory only

c) For CAREVision only

d) Depending on scan protocol selections, not all combinations shown are selectable

e) For Multiscan only

According to:

21 CFR 1020.33 (c)(3)(v)

Tolerances of slice thickness:

0.6 mm	Tolerance: ± 0.3 mm
0.75 mm	Tolerance: ± 0.5 mm
1 - 2 mm	Tolerance: ± 50 %
> 2 mm	Tolerance: ± 1.0 mm

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CE
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Manufacturer's note:

This device bears a CE mark in accordance with the provisions of Council Directive 93/42/EEC of June 14, 1993 concerning medical devices and the Council Directive 2011/65/EU of June 08, 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

The CE marking applies only to Medical Devices which have been put on the market according to the above-mentioned EC Directives.

Unauthorized changes to this product are not covered by the CE mark and the related Declaration of Conformity.

Products with serial numbers between 59401 and 59519 or 77701 and 77869 may contain RoHS non-conforming material, and therefore are not covered by the respective Declaration of Conformity.

Federal law restricts this device to sale by or on the order of a physician (21 CFR 801.109(b)(1)).

The original language of this document is English.

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Print No. HC-C2-S68-G.660.01.01.02 | © Siemens Healthcare GmbH, 2016

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