

URGENT – Medical Device Correction
Brilliance CT Systems and
Gemini and Precedence Systems utilizing Brilliance CT

Issues with the CTDI_{vol} Factors on Philips CT Systems

Dear Customer,

A problem has been detected in the Philips Brilliance CT Systems and Gemini and Precedence Systems utilizing Brilliance CT that if it were to re-occur, could pose a risk for patients or users.

This Field Safety Notice 72800599_88200461 is intended to inform you about:

- what the problem is and under what circumstances it can occur,
- the actions that should be taken by the customer / user in order to prevent risks for patients or users,
- the actions planned by Philips to correct the problem.

This document contains important information for the continued safe and proper use of your equipment

Please review the following information with all members of your staff who need to be aware of the contents of this communication. It is important to understand the implications of this communication.

Please retain a copy with the equipment instruction for Use.

If you need any further information or support concerning these issues, please contact your local Philips representative or local Philips Healthcare office.

For North America and Canada contact the Customer Care Solutions Center (1-800-722-9377, option 5; Enter Site ID or follow the prompts).

This notice has been reported to the appropriate Regulatory Agencies.

Philips apologizes for any inconveniences caused by this problem.

Sincerely,



Michael McAndrew
Senior Director, Quality and Regulatory



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AFFECTED PRODUCTS	<p>Gemini Dual, Gemini 16 Power, Gemini GXL, Gemini LXL, Gemini TF 16, Gemini TF Base/Ready, Gemini TF 64, Gemini TF Big Bore <u>Product Code(s):</u> 882160, 882300, 882390, 882400, 882410, 882412, 882470, 882473, 882471, 882476</p> <p>Precedence SPECT/CT <u>Product Code(s):</u> 882350, 882351</p> <p>Brilliance CT (6, 10, 16, 16P, 40, 64 and Big Bore), Brilliance iCT, Brilliance iCT SP <u>Product Code(s):</u> 728256, 728251, 728246, 728240, 728235, 728231, 728243, 728244, 728306, 728311</p>
PROBLEM DESCRIPTION	The stated tolerance for CTDI _{vol} in the Instructions for Use Manual did not accurately represent all systems. On some systems the measured CTDI _{vol} value may fall outside of these stated tolerances.
HAZARD INVOLVED	On some systems the measured CTDI _{vol} value may fall outside of the stated tolerances. Under certain circumstances the measured CTDI _{vol} value is estimated to be less than or equivalent to one rescan.
HOW TO IDENTIFY AFFECTED PRODUCTS	Customers in receipt of this notification are affected, and have been identified as the operator/user. Please refer to the "Affected Products" section of this letter for a complete product listing.
ACTION TO BE TAKEN BY CUSTOMER / USER	<ul style="list-style-type: none"> • Please refer to the attached addendum which clarifies the published specifications and correlation of CTDI_{vol} value measurements. • The information in this Addendum, titled "ADDENDUM: Factors that Affect CTDI_{vol} on Philips CT Systems" replaces any CTDI_{vol} information that you currently have with your system. • This letter and the addendum must be placed in your User Documentation until otherwise notified.
ACTIONS PLANNED BY PHILIPS	Attached to this correspondence please find a document titled "ADDENDUM: Factors that Affect CTDI _{vol} on Philips CT Systems". This information should clarify CTDI _{vol} tolerances.
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact your local Philips representative. In the United States and Canada, please contact the Philips Healthcare Customer Care Solutions Center at 1-800-722-9377 and follow the recorded menu options to reach a Customer Solutions Engineer; in all other countries please dial your local Philips Healthcare office.



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CTDI_{vol} Factors on Philips CT Systems

The following factors affect the precision and accuracy of CTDI_{vol} measurements on Philips CT scanners:

Dosimeter Calibration

Dosimeter probes used for CTDI_{vol} measurement can have variable calibration. The usual manufacturer specified tolerance is $\pm 5\%$. Many authorized traceable calibration laboratories calibrate dosimeters to this $\pm 5\%$ tolerance as well.

CTDI Measurement Instructions

Philips Phantom recommended positioning and CTDI₁₀₀, CTDI_w and CTDI_{vol} measurement and calculation instructions:

The Head phantom should be installed on the nominal head holder of the scanner used for patient scanning. The Body phantom is installed on the couch top table. Each phantom should be properly centered within $\pm 3\text{mm}$ in axial plane. Along the axis of the couch the beam should go through the phantom center within $\pm 2\text{mm}$. The phantom horizontal axis shall be aligned parallel to scanner rotation axis within $\pm 3^\circ$. To check this first and last slice center position shall be compared.

The measurement positions are defined in Figure-1. The dose probe is inserted consecutively in each position and axial 360° rotation scans are performed at desired mAs, kV and other scan parameters.

For better accuracy a number of scans are performed at each location and the result is averaged.

The X-ray is activated a few milliseconds before data acquisition there is some overlap of X-ray beam between start and end of the scan. This results in variable peripheral measurements dependent on the location of the x-ray beam-on overlap relative to the measurement probe position. The observed variation is typically on the order of around 10%. Due to this phenomenon for peripheral positions at least 10 scans shall be used and the measured values shall be averaged. At the center position at least 5 scans shall be averaged. The person taking the measurements must examine the results being obtained to verify that the number of samples for each position is appropriate and that all positions use the same number of samples.

Variance and Standard deviation are determined through a variety of measurement techniques and multiple measurements.



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Although both dose profile integrals are measured using the same acrylic head and body phantoms, the CTDI₁₀₀ index specifies absorbed dose to air rather than absorbed dose to acrylic. The formula used to calculate the CTDI₁₀₀ is

$$(1) \quad CTDI_{100} = \frac{1}{N \cdot T(cm)} \cdot Dose(mGy)$$

Appropriate conversion factors from other units of radiation exposure measure may be used to ensure that the readings are in mGy.

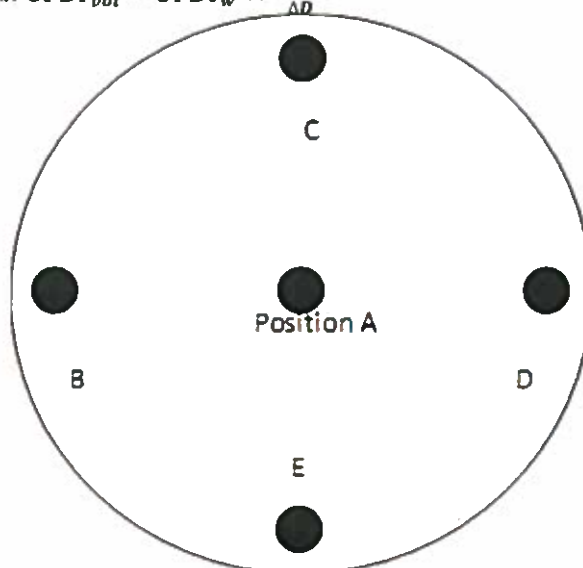
The CTDI_w (CTDI weighted) is then calculated as follows.

$$(2) \quad CTDI_w = 1/3 \cdot CTDI_{100_center} + 2/3 \cdot CTDI_{100_peripheral}$$

The CTDI_{vol} (CTDI volume) is then calculated as follows.

Helical: $CTDI_{vol} = CTDI_w + Pitch\ Factor$

Axial: $CTDI_{vol} = CTDI_w \times \frac{(N \times T)}{AD}$



The graphics shows holes positions used for CTDI₁₀₀ measurement. The dosimetric probe is inserted in each position in turn and the scan is performed.

During the measurement the probe is inserted in one of the holes of the phantom and all other holes must be filled by PMMA rods supplied with the phantom.



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Variability between CT Scanners

There are variations between individual systems as they are manufactured as well as during the life of the system. There are three typical causes for these variations.

The first - is variation in x-ray output. This is due to variation in new tube output, a decline in output due to normal aging of components such as the x-ray tube, and by variations in the high voltage generator output. As a system's x-ray tube ages the output of dose per mA will typically decline along with a change in the beam quality.

The second - is variability within the components or the behavior of the components, particularly those located in the path of the beam. These materials have variations in composition and thickness much like any other manufactured material. These variations combine and alter the amount and the quality of radiation that is emitted.

The third – is that the beam collimator has some amount of uncertainty which results in part of the variability described here. The collimator blade position uncertainty is small relative to the commanded openings and does not vary proportionally with commanded openings; therefore it has the greatest effect on the smallest collimator settings where it can contribute a proportionally larger fraction of the total anticipated reading.

The final CTDI_{vol} tolerances are calculated in a statistical manner namely by combining the various deviations as independent random variables. The logic behind this approach is that it is statistically unlikely that all deviations will be at their maximum and to the same direction (such as the tube output being higher than usual, all the x-ray filters being thinner, etc). The stated tolerances fit the well-known "3 sigma" criterion, namely the CTDI of ~99% of the scanners are within the stated tolerances. The tolerance for CTDI_{vol} and CTDI₁₀₀ are identical, and are listed in the tables provided.



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New CTDI_{vol} Tolerances for Each System

Big Bore, Gemini TF Big Bore

Collimation	kVp	CTDI _{vol} Head spec @ 250 mAs (unchanged)	CTDI _{vol} Body spec @ 250 mAs (unchanged)	CTDI _{vol} spec tolerance (Previously 20%)
16x1.5	90	11.53	5.81	30%
8x3	90	11.53	5.81	30%
4x4.5	90	11.53	5.81	30%
4x3	90	12.68	5.81	30%
16x0.75	90	12.68	6.39	30%
4x1.5	90	13.83	6.97	30%
4x0.75	90	19.6	9.88	30%
2x0.6	90	17.29	8.13	38%
16x1.5	120	25.4	13.2	30%
8x3	120	25.4	13.2	30%
4x4.5	120	25.4	13.2	30%
4x3	120	27.94	13.2	30%
16x0.75	120	27.94	14.52	30%
4x1.5	120	30.48	15.84	30%
4x0.75	120	43.18	22.44	30%
2x0.6	120	38.1	18.48	38%
16x1.5	140	36.91	19.08	30%
8x3	140	36.91	19.08	30%
4x4.5	140	36.91	19.08	30%
4x3	140	40.6	19.08	30%
16x0.75	140	40.6	20.99	30%
4x1.5	140	44.29	22.9	30%
4x0.75	140	62.74	32.44	30%
2x0.6	140	55.36	26.72	38%



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Brilliance 64, Gemini TF 64

Collimation	kVp	CTDI _{vol} Head spec @ 250 mAs (unchanged)	CTDI _{vol} Body spec @ 250 mAs (unchanged)	CTDI _{vol} spec tolerance (Previously 20%)
64x0.625	80	8.89	4.5	25%
32x1.25	80	8.89	4.5	25%
16x2.5	80	8.68	4.39	25%
40x0.625	80	10.58	5.36	25%
12x1.25	80	10.69	5.46	25%
20x0.625	80	11.85	6.05	25%
16x0.625	80	12.49	6.37	25%
12x0.625	80	12.91	6.59	25%
2x0.625	80	21.17	10.71	30%
2x0.5	80	NA	NA	NA
64x0.625	120	28.63	14.7	25%
32x1.25	120	28.63	14.7	25%
16x2.5	120	27.95	14.35	25%
40x0.625	120	34.08	17.5	25%
12x1.25	120	34.42	17.85	25%
20x0.625	120	38.17	19.78	25%
16x0.625	120	40.22	20.83	25%
12x0.625	120	41.58	21.53	25%
2x0.625	120	68.17	35	30%
2x0.5	120	85.21	43.75	30%
64x0.625	140	41.71	21.87	25%
32x1.25	140	41.71	21.87	25%
16x2.5	140	40.72	21.35	25%
40x0.625	140	49.65	26.04	25%
12x1.25	140	50.15	26.56	25%
20x0.625	140	55.61	29.43	25%



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16x0.625	140	58.59	30.99	25%
12x0.625	140	60.58	32.03	25%
2x0.625	140	99.31	52.08	30%
2x0.5	140	124.14	65.1	30%

iCT, iCT SP Adult Mode

Collimation	kVp	CTDI _{vol} Head spec @ 250 mAs (unchanged)	CTDI _{vol} Body spec @ 250 mAs (unchanged)	CTDI _{vol} spec tolerance (Previously 20%)
128x0.625	80	9.1	4.55	35%
128x0.625	100	18.5	9.45	35%
128x0.625	120	30.16	15.76	35%
128x0.625	140	44.05	23.26	35%
64x1.25	80	9.19	4.55	35%
64x1.25	100	18.69	9.45	35%
64x1.25	120	30.46	15.76	35%
64x1.25	140	44.49	23.26	35%
64x0.625	80	10.1	4.96	35%
64x0.625	100	20.54	10.3	35%
64x0.625	120	33.47	17.18	35%
64x0.625	140	48.9	25.36	35%
32x1.25	80	10.1	4.96	35%
32x1.25	100	20.54	10.3	35%
32x1.25	120	33.47	17.18	35%
32x1.25	140	48.9	25.36	35%
32x0.625	80	12.01	5.73	35%
32x0.625	100	24.42	11.9	35%
32x0.625	120	39.81	19.86	35%
32x0.625	140	58.15	29.31	35%
20x0.625	80	12.56	6.33	35%



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20x0.625	100	25.53	13.15	35%
20x0.625	120	41.62	21.94	35%
20x0.625	140	60.79	32.38	35%
16x0.625	80	13.92	6.32	35%
16x0.625	100	28.31	13.13	35%
16x0.625	120	46.14	21.91	35%
16x0.625	140	67.4	32.34	35%
8x0.625	80	NA	7.64	35%
8x0.625	100	NA	15.87	35%
8x0.625	120	NA	26.48	35%
8x0.625	140	NA	39.08	35%
4x0.625	80	13.56	7.05	40%
4x0.625	100	27.57	14.64	40%
4x0.625	120	44.93	24.43	40%
4x0.625	140	65.64	36.06	40%
2x0.625	80	13.74	6.96	40%
2x0.625	100	27.94	14.45	40%
2x0.625	120	45.54	24.12	40%
2x0.625	140	66.52	35.59	40%

iCT, iCT SP Infant Mode

Collimation	kVp	CTDI _{vol} Head spec @ 250 mAs (unchanged)	CTDI _{vol} Body spec @ 250 mAs (unchanged)	CTDI _{vol} spec tolerance (Previously 20%)
128x0.625	80	11.37	4.88	40%
128x0.625	100	21.87	9.82	40%
128x0.625	120	35.81	15.59	40%



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Collimation	kVp	CTDI _{vol} Head spec @ 250 mAs (unchanged)	CTDI _{vol} Body spec @ 250 mAs (unchanged)	CTDI _{vol} spec tolerance (Previously 20%)
64x1.25	80	11.49	4.88	40%
64x1.25	100	22.09	9.82	40%
64x1.25	120	36.17	15.59	40%
112x0.625	80	NA	4.88	40%
112x0.625	100	NA	9.82	40%
112x0.625	120	NA	15.59	40%
96x0.625	80	NA	4.88	40%
96x0.625	100	NA	9.82	40%
96x0.625	120	NA	15.59	40%
64x0.625	80	12.62	5.32	40%
64x0.625	100	24.28	10.7	40%
64x0.625	120	39.75	16.99	40%
32x1.25	80	12.62	5.32	40%
32x1.25	100	24.28	10.7	40%
32x1.25	120	39.75	16.99	40%
32x0.625	80	15.01	6.14	40%
32x0.625	100	28.87	12.37	40%
32x0.625	120	47.27	19.64	40%
20x0.625	80	15.7	6.79	40%
20x0.625	100	30.18	13.67	40%
20x0.625	120	49.42	21.7	40%
16x0.625	80	17.4	6.78	40%
16x0.625	100	33.46	13.65	40%
16x0.625	120	54.79	21.67	40%
8x0.625	80	NA	8.19	40%
8x0.625	100	NA	16.5	40%
8x0.625	120	NA	26.19	40%
4x0.625	80	16.95	7.56	45%



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Collimation	kVp	CTDI _{vol} Head spec @ 250 mAs (unchanged)	CTDI _{vol} Body spec @ 250 mAs (unchanged)	CTDI _{vol} spec tolerance (Previously 20%)
4x0.625	100	32.59	15.22	45%
4x0.625	120	53.36	24.16	45%
2x0.625	80	17.17	7.46	50%
2x0.625	100	33.02	15.02	50%
2x0.625	120	54.07	23.85	50%

iCT, iCT SP Cardiac Mode

Collimation	kVp	CTDI _{vol} Head spec @ 250 mAs (unchanged)	CTDI _{vol} Body spec @ 250 mAs (unchanged)	CTDI _{vol} spec tolerance (Previously 20%)
128x0.625	80	NA	4.27	30%
128x0.625	100	NA	8.87	30%
128x0.625	120	NA	14.81	30%
128x0.625	140	NA	21.88	30%
64x1.25	80	NA	4.27	30%
64x1.25	100	NA	8.87	30%
64x1.25	120	NA	14.81	30%
64x1.25	140	NA	21.88	30%
112x0.625	80	NA	4.27	30%
112x0.625	100	NA	8.87	30%
112x0.625	120	NA	14.81	30%
112x0.625	140	NA	21.88	30%
96x0.625	80	NA	4.27	30%
96x0.625	100	NA	8.87	30%
96x0.625	120	NA	14.81	30%
96x0.625	140	NA	21.88	30%



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Collimation	kVp	CTDI _{vol} Head spec @ 250 mAs (unchanged)	CTDI _{vol} Body spec @ 250 mAs (unchanged)	CTDI _{vol} spec tolerance (Previously 20%)
64x0.625	80	NA	4.65	30%
64x0.625	100	NA	9.66	30%
64x0.625	120	NA	16.15	30%
64x0.625	140	NA	23.85	30%
32x1.25	80	NA	4.65	30%
32x1.25	100	NA	9.66	30%
32x1.25	120	NA	16.15	30%
32x1.25	140	NA	23.85	30%
32x0.625	80	NA	5.38	38%
32x0.625	100	NA	11.17	38%
32x0.625	120	NA	18.66	38%
32x0.625	140	NA	27.56	38%
20x0.625	80	NA	NA	NA
20x0.625	100	NA	NA	NA
20x0.625	120	NA	NA	NA
20x0.625	140	NA	NA	NA
16x0.625	80	NA	5.93	38%
16x0.625	100	NA	12.32	38%
16x0.625	120	NA	20.59	38%
16x0.625	140	NA	30.41	38%



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iCT, iCT SP Trauma Mode

Collimation	kVp	CTDI _{vol} Head spec @ 250 mAs (unchanged)	CTDI _{vol} Body spec @ 250 mAs (unchanged)	CTDI _{vol} spec tolerance (Previously 20%)
128x0.625	80	NA	NA	NA
128x0.625	100	NA	NA	NA
128x0.625	120	NA	28.95	30%
128x0.625	140	NA	41.27	30%
64x1.25	80	NA	NA	NA
64x1.25	100	NA	NA	NA
64x1.25	120	NA	28.95	30%
64x1.25	140	NA	41.27	30%
64x0.625	80	NA	NA	NA
64x0.625	100	NA	NA	NA
64x0.625	120	NA	31.55	30%
64x0.625	140	NA	44.98	30%
32x1.25	80	NA	NA	NA
32x1.25	100	NA	NA	NA
32x1.25	120	NA	31.55	30%
32x1.25	140	NA	44.98	30%
32x0.625	80	NA	NA	NA
32x0.625	100	NA	NA	NA
32x0.625	120	NA	36.47	30%
32x0.625	140	NA	52	30%



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Brilliance 16, Gemini 16 Power, Gemini GXL, Gemini LXL, Gemini TF 16, Gemini TF Base/Ready, Precedence SPECT/CT

Collimation	kVp	CTDI _{vol} Head spec @ 250 mAs (unchanged)	CTDI _{vol} Body spec @ 250 mAs (unchanged)	CTDI _{vol} spec tolerance (Previously 20%)
16x1.5	90	16.05	7.61	35%
8x3	90	16.05	7.61	35%
4x4.5	90	16.05	7.61	35%
4x3	90	17.65	8.38	35%
16x0.75	90	17.65	8.38	35%
4x1.5	90	20.86	9.9	38%
4x0.75	90	28.89	13.7	38%
2x0.6	90	22.47	10.66	50%
16x1.5	120	34.6	17.62	35%
8x3	120	34.6	17.62	35%
4x4.5	120	34.6	17.62	35%
4x3	120	38.06	19.38	35%
16x0.75	120	38.06	19.38	35%
4x1.5	120	44.98	22.9	38%
4x0.75	120	62.28	31.71	38%
2x0.6	120	48.44	24.66	50%
16x1.5	140	49.69	27.45	35%
8x3	140	49.69	27.45	35%
4x4.5	140	49.69	27.45	35%
4x3	140	54.66	30.2	35%
16x0.75	140	54.66	30.2	35%
4x1.5	140	64.6	35.69	38%
4x0.75	140	89.45	49.41	38%
2x0.6	140	69.57	38.43	50%



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Brilliance 40

Collimation	kVp	CTDI _{vol} Head spec @ 250 mAs (unchanged)	CTDI _{vol} Body spec @ 250 mAs (unchanged)	CTDI _{vol} spec tolerance (Previously 20%)
32x1.25	80	3.56	1.8	30%
16x2.5	80	3.47	1.76	30%
40x0.625	80	2.65	1.34	30%
12x1.25	80	1.6	0.82	30%
20x0.625	80	1.48	0.76	30%
16x0.625	80	1.25	0.64	30%
12x0.625	80	0.97	0.49	30%
2x0.625	80	0.34	0.17	40%
2x0.5	80	0.28	0.14	40%
32x1.25	120	11.45	5.88	30%
16x2.5	120	11.18	5.74	30%
40x0.625	120	8.52	4.38	30%
12x1.25	120	5.16	2.68	30%
20x0.625	120	4.77	2.47	30%
16x0.625	120	4.02	2.08	30%
12x0.625	120	3.12	1.61	30%
2x0.625	120	1.09	0.57	40%
2x0.5	120	0.9	0.47	40%
32x1.25	140	16.68	8.75	30%
16x2.5	140	16.29	8.54	30%
40x0.625	140	12.41	6.51	30%
12x1.25	140	7.52	3.98	30%
20x0.625	140	6.95	3.68	30%
16x0.625	140	5.86	3.1	30%
12x0.625	140	4.54	2.4	30%
2x0.625	140	1.59	0.85	40%
2x0.5	140	1.31	0.69	40%



URGENT – Medical Device Correction
Brilliance CT Systems and
Gemini and Precedence Systems utilizing Brilliance CT

ADDENDUM

CTDI_{vol} Factors on Philips CT Systems

Brilliance 6

Collimation	kVp	CTDI _{vol} Head spec @ 250 mAs (unchanged)	CTDI _{vol} Body spec @ 250 mAs (unchanged)	CTDI _{vol} spec tolerance (Previously 20%)
6x4	90	15.27	7.19	35%
6x3	90	16.79	7.91	35%
6x1.5	90	18.32	8.63	35%
6x.75	90	22.9	10.79	38%
4x.75	90	27.48	12.94	38%
2x0.6	90	24.43	11.51	50%
6x4	120	32.92	16.65	35%
6x3	120	36.21	18.31	35%
6x1.5	120	39.5	19.98	35%
6x.75	120	49.38	24.97	38%
4x.75	120	59.25	29.96	38%
2x0.6	120	52.67	26.63	50%
6x4	140	47.28	25.94	35%
6x3	140	52	28.53	35%
6x1.5	140	56.73	31.12	35%
6x.75	140	70.91	38.9	38%
4x.75	140	85.1	46.68	38%
2x0.6	140	75.64	41.5	50%

