

## FIELD SAFETY NOTICE

<b>Subject:</b>	<b>Revised Dose Area Product (DAP) values for CBCT scans</b>
<b>Product(s) affected:</b>	3Shape X1 models X1-WL, X1-WR, X1-FL, X1-FR; version 1.1
<b>Function(s) affected:</b>	The issue is related to DAP values for CBCT scans; Panoramic scan DAP values are not affected
<b>Date of notification:</b>	21 September 2018
<b>Individual notifying:</b>	Yaron Levy, Scientific Manager (Regulatory Affairs), 3Shape
<b>3Shape reference:</b>	CAS-229454-K5W2Q8
<b>FSN reference:</b>	FSN2018-001/1
<b>Type of action:</b>	<b>Updated information regarding safe use of the device</b>

Dear 3Shape Customer,

We are writing to advise you that the Dose Area Product (DAP) values provided for CBCT scans with the 3Shape X1 scanner are not accurate. This pertains to DAP values

- displayed in the 3Shape X1 User Interface when specific scan settings are selected,
- recorded in the DICOM image file data,
- and stated in the Safety and Setup Guide

### Background:

DAP values were measured with a newly-calibrated dose meter and found to be higher than the DAP values presented in the current labelling of the product. Depending on the specific patient-size, FOV, and image-quality setting of the scanner, the increases vary (see Appendix for exact amounts). The cause of the issue was found to be failure by the manufacturer of the dose meter to apply a correction factor after calibrating the instrument, and not related to a change in the performance of the X1 scanner.

This Field Safety Notice is to provide you with corrective action information, and to advise you of the actions 3Shape is taking to address the issue.

### Effect:

The amount of X-ray radiation emitted by the scanner at each CBCT scan setting is unchanged. However, the revised DAP values for each setting are higher than those currently stated. The exact amount of increased value depends on the combination of patient-size, FOV, and image-quality settings used.

The effect of this issue is that when a User/Operator of the X1 scanner performs a CBCT scan they will be presented with lower DAP values than those actually being emitted. Since these DAP values may contribute to assessing the justification for performing a CBCT scan or not (or for using particular image quality settings), as well as for the continuous optimization of dose and clinical image quality as part of a Quality Assurance Program, it is important that the presented DAP values reflect as closely as possible the true amounts emitted by the device.

**Potential harm:**

**The currently-presented DAP values, which are underestimated, could lead to bias towards conducting a CBCT scan, or a scan at higher image-quality settings than would otherwise be chosen, and thereby lead to potentially higher X-ray exposures to the patient.**

**User / Operator Corrective Actions:**

- 1) With immediate effect, always refer to the revised DAP values provided in the attached Appendix when performing, or considering to perform, CBCT scans. Refer to the revised DAP value for the specific patient-size, FOV, and image-quality settings that you are using (or considering using).
- 2) Inform all Users/Operators of the 3Shape X1 scanner at your site of the revised DAP values.
- 3) Confirm receipt of this Field Safety Notice by signing and returning the enclosed Confirmation of Receipt Form. Email the form to: [Ednan.Ramicic@3shape.com](mailto:Ednan.Ramicic@3shape.com)

**3Shape Corrective Actions:**

- 1) With immediate effect, 3Shape is providing you with the revised DAP values provided in the attached Appendix.
- 2) 3Shape will implement a permanent solution within 6 months. The solution will be in the form of:
  - Software update
  - Safety and Setup Guide update

These updates will be available via your Reseller/Partner who supplied your 3Shape X1 scanner.

**Please inform the appropriate personnel working in your department of the contents of this letter.**

You can safely continue using your 3Shape X1 scanner, referring to the revised DAP values provided in the Appendix attached to this letter.

We sincerely apologize for any inconvenience and thank you in advance for your co-operation.

If you require further clarification, please contact the Reseller/Partner who supplied your 3Shape X1 scanner.

Kind Regards,

Yaron Levy



21 September 2018

## Appendix

**REVISED**

**Dose-Area Product table for CBCT scans**

ID	Patient size	Image quality	DAP (mGy•cm <sup>2</sup> )				
			∅ 20 x 20 mm	∅ 40 x 40 mm	∅ 50 x 50 mm	∅ 80 x 50 mm	∅ 80 x 80 mm
1	Child	Low dose	22	65	94	143	216
2	Child	Normal	41	119	173	262	397
3	Child	High	57	166	242	367	556
4	Child	Ultra high	76	222	324	–	–
5	Adolescent	Low dose	26	74	108	164	248
6	Adolescent	Normal	48	139	202	306	463
7	Adolescent	High	67	194	283	428	649
8	Adolescent	Ultra high	89	260	378	–	–
9	Adult	Low dose	28	81	119	180	272
10	Adult	Normal	55	159	232	351	531
11	Adult	High	80	231	337	510	773
12	Adult	Ultra high	106	309	450	–	–
13	Large Adult	Low dose	30	87	126	191	290
14	Large Adult	Normal	70	205	298	451	683
15	Large Adult	High	99	289	421	638	966
16	Large Adult	Ultra high	133	386	563	–	–

## OBSOLETE

**Dose-Area Product table for CBCT scans**

ID	Patient size	Image quality	DAP (mGy•cm <sup>2</sup> )				
			∅ 20 x 20 mm	∅ 40 x 40 mm	∅ 50 x 50 mm	∅ 80 x 50 mm	∅ 80 x 80 mm
1	Child	Low dose	12	42	64	98	155
2	Child	Normal	20	69	105	162	254
3	Child	High	27	92	139	215	338
4	Child	Ultra high	35	119	180	–	–
5	Adolescent	Low dose	14	49	73	114	178
6	Adolescent	Normal	26	87	131	204	320
7	Adolescent	High	34	117	177	274	429
8	Adolescent	Ultra high	45	152	230	–	–
9	Adult	Low dose	16	55	83	129	202
10	Adult	Normal	31	106	161	249	390
11	Adult	High	42	142	214	332	521
12	Adult	Ultra high	55	186	280	–	–
13	Large Adult	Low dose	19	64	96	149	233
14	Large Adult	Normal	36	122	184	285	448
15	Large Adult	High	48	162	245	379	594
16	Large Adult	Ultra high	62	212	321	–	–

## Confirmation of Receipt of Field Safety Notice

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<b>3Shape reference:</b>	CAS-229454-K5W2Q8
<b>FSN reference:</b>	FSN2018-001/1
<b>Date of FSN:</b>	21-SEP-2018
<b>Product(s) affected:</b>	3Shape X1 models X1-WL, X1-WR, X1-FL, X1-FR; version 1.1

By signing below, I acknowledge that the required actions have been taken in accordance with this Field Safety Notice.

**Printed name:** \_\_\_\_\_ **Signature:** \_\_\_\_\_

**Title:** \_\_\_\_\_ **Telephone:** \_\_\_\_\_

**Date (DD/MM/YYYY):** \_\_\_\_ / \_\_\_\_ / \_\_\_\_\_

**Facility name:** \_\_\_\_\_

**Facility address:** \_\_\_\_\_

**City:** \_\_\_\_\_ **Country:** \_\_\_\_\_

It is important that you and your organisation takes the actions detailed in the FSN and confirm that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.

**Email the complete form to:** [Ednan.Ramicic@3shape.com](mailto:Ednan.Ramicic@3shape.com)