

### DEMO

110 Wild Basin Rd Austin TX 78746 (512) 334-5490

Patient Name:	Spondy, Steve
DOB:	03/03/1982
Date of Imaging:	<u>6/21/2016</u>
Referring Physician:	OKI Admin MD G Malcolmson

### Lumbar Spine Motion X-ray Disability Assessment Report

### Technique

Patient was referred for Vertebral Motion Analysis (VMA) testing to assess for potential Lumbar radiographic instability. The purpose of the test is to evaluate ligament injury by alteration of motion segment integrity (AOMSI) documenting increased translational or angular motion per DRE category: (5th Ed AMA p.384). VMA testing was conducted, which involves the use of FDA-cleared software to measure the relative motion of vertebral bodies on radiographic images acquired during patient bending of the Lumbar spine. VMA software is intended to assist physicians and clinical professionals in the analysis of vertebral body motion in musculoskeletal images of the spine, and permits users to generate a 'motion analysis' report containing graphics, charts, and text. VMA measurements of intervertebral angulation and translation have been validated to be more accurate and precise as compared to standard methods for taking these measurements.

Subsequent radiological interpretation of images and processed results was performed to assess for the presence of potential radiographic instability.

### Findings

L1/L2: The maximum translation at this level was 4.5 mm (14% of vertebral body depth), this is evidence of translational instability according to the medical literature. The maximum angular motion at this level was 15 degrees. This angulation measurement exceeds the threshold for AOMSI of 15 degrees, the measurement for translation exceeds the threshold for AOMSI of 4.5 mm, each of these therefore demonstrating evidence of radiographic instability and ligamentous injury.

L2/L3:Maximum translation was 3.7 mm (11% of vertebral body depth). The maximum angular motion at this level was 18 degrees. This angulation measurement exceeds the threshold for AOMSI of 15 degrees, therefore demonstrating evidence of radiographic instability and ligamentous injury.

L3/L4:Maximum translation was 3.3 mm (9% of vertebral body depth). The maximum angular motion at this level was 14 degrees. These values do not exceed any thresholds for AOMSI as referenced above.

L4/L5:Maximum translation was 3.7 mm (10% of vertebral body depth). The maximum angular motion at this level was 11 degrees. These values do not exceed any thresholds for AOMSI as referenced above.

L5/S1:Maximum translation was 7.5 mm (20% of vertebral body depth). The maximum angular motion at this level was 10 degrees. This measurement for translation exceeds the threshold for AOMSI of 4.5 mm, therefore demonstrating evidence of radiographic instability and ligamentous injury.

### Impression

Evidence of radiographic instability and ligamentous injury is demonstrated. Loss of motion segment integrity due to excessive intervertebral translation is confirmed at L1/L2 by the measured value of 4.5 millimeters (14%) of relative motion, which exceeds the threshold for impairment of the Lumbar spine as specified in the AMA Guides (Fifth Edition, 2000) and is consistent with a whole person impairment rating of 20% to 23%. Evidence of radiographic instability and ligamentous injury is demonstrated. Loss of motion segment integrity due

Evidence of radiographic instability and ligamentous injury is demonstrated. Loss of motion segment integrity due to excessive intervertebral angulation is confirmed at L1/L2 by the measured value of 15 degrees of relative motion, which exceeds the threshold for impairment of the Lumbar spine as specified in the AMA Guides (Fifth Edition, 2000) and is consistent with a whole person impairment rating of 20% to 23%.

Evidence of radiographic instability and ligamentous injury is demonstrated. Loss of motion segment integrity due to excessive intervertebral angulation is confirmed at L2/L3 by the measured value of 18 degrees of relative motion, which exceeds the threshold for impairment of the Lumbar spine as specified in the AMA Guides (Fifth Edition, 2000) and is consistent with a whole person impairment rating of 20% to 23%.

Evidence of radiographic instability and ligamentous injury is demonstrated. Loss of motion segment integrity due to excessive intervertebral translation is confirmed at L5/S1 by the measured value of 7.5 millimeters (20%) of relative motion, which exceeds the threshold for impairment of the Lumbar spine as specified in the AMA Guides (Fifth Edition, 2000) and is consistent with a whole person impairment rating of 20% to 23%.

Signed by: OKI\_Admin\_MD G Malcolmson, on 8/10/2019 at 9:46 AM CST

### Vertebral Motion Analysis<sup>™</sup> Lumbar Report

PATIENT: Spondy, StevePATIENT ID: 1563124DOB: 03/03/1982STUDY DATE: 6/21/2016IMAGING EVENT ID: 58010ACCESSION No: 19820303PRESCRIBING PHYSICIAN: G Malcolmson, OKI\_Admin\_MDTEST CENTER: Statera Spine Demo

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A WARNING: Inadequate tracking of vertebral bodies across radiographic images can lead to erroneous results. Image data and template placement must be reviewed prior to accepting any measurement results. If any templates are found to be incorrectly placed on vertebral bodies, any associated measurements should not be utilized in clinical decision making.

🔼 WARNING: When being viewed on a computer, a diagnostic-quality image review workstation should be used



# VMA<sup>™</sup> Report Lumbar Motion Analysis Summary

PATIENT: Spondy, Steve PATIENT ID: 1563124 DOB: 03/03/1982 STUDY DATE: 6/21/2016 IMAGING EVENT ID: 58010 ACCESSION No: 19820303 PRESCRIBING PHYSICIAN: G Malcolmson, OKI\_Admin\_MD TEST CENTER: Statera Spine Demo PATIENT LEVEL ALERTS: NONE

	MAX TRAN	NSLATION CHANGE BETWEEN VIEWS <sup>2</sup>	MAX ANGU FLEX/EXT	JLATION <sup>3</sup> LEFT/RIGHT	DISC HEIGHT <sup>4</sup> CENTERLINE	INSTRUMENTED LEVELS <sup>5</sup> MAX. CONFIRMABLE ANGULATION
L1/L2	-2.2 mm -7% CLE	(m) 4.5 mm CLE-USN 14%	<b>▲ 15°</b> cs	<b>17°</b> cs	9.2 mm	n/a
L2/L3	-2.7 mm USN -8%	3.7 mm <sub>CLF-USN</sub> 11%	<u>▲ 18°</u> cs	<b>15°</b> us	8.7 mm	n/a
L3/L4	-3.3 mm <sub>CSF</sub>	<b>2.8 mm</b> CSN-CSF 8%	<b>14°</b> cs	<b>14°</b> CL	9.3 mm	n/a
L4/L5	-3.7 mm <sub>CSE</sub>	<b>2.9</b> mm <sub>CSN-CLE</sub> 8%	<b>11°</b> CL	<b>13°</b> CL	13.2 mm	n/a
L5/S1	<b>7.5</b> mm USF <b>20%</b>	▲ 4.1 mm CLF-USF 11%	<b>10°</b> CL	4° CL	6.9 mm	n/a
N/A	n/r	n/r	n/r	n/r	n/r	n/a

Potential mal-alignment or KEY: excessive motion\*

Potential borderline mal-alignment 🛛 🙌 Potential residual motion at a or excessive motion\*

Potential sagittal alignment issue

\*NOTE: The letters 'FN' appearing within these alert icons indicates an alert that was triggered only in the device assisted bending images. If only uncontrolled bending images had been consulted, a potential "false negative" result for the underlying anomaly would have occurred.

FIRST LETTER: Controlled (C) vs. Uncontrolled (U) bending. SECOND LETTER: Standing (S) vs. Lying (L) bending. THIRD LETTER: Flexion (F), Extension (E), Patient Left (L), Patient Right (R), or Neutral (N) view. XTP = Cross table prone. XTS = Cross table supine. LTM = Less than minimum motion threshold. See Quantitative Definitions page of this report package for further definition and reference thresholds. See Endnotes page for all footnotes.

fusion level

Vertebral Motio

# VMA<sup>™</sup> Report Lumbar Sagittal Alignment

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	MAX. FLEX*	LORDOSIS ANGLE <sup>15</sup> STANDING NEUTRAL	MAX. EXT*	ANTERIOR (MIN MAX)	DISC HEIGHT <sup>4</sup> CENTERLINE	POSTERIOR (MIN MAX)
L1/L2	12°	6°	-2°	10.8 mm (7.9 13.1)	9.2 mm	7.9 mm (5.1 10.5)
L2/L3	13°	9°	-5°	11.1 mm (7.2 15.1)	8.7 mm	6.3 mm (6.3 10.1)
L3/L4	14°	10°	-1°	12.5 mm (8.8 14.7)	9.3 mm	6.2 mm (6.2 10.2)
L4/L5	19°	-16°	-16°	18.0 mm (11.9 20.1)	13.2 mm	8.4 mm (6.4 12.7)
L5/S1	7°	2°	-3°	6.4 mm (4.2 10.6)	6.9 mm	7.4 mm (6.3 10.0)
N/A	n/r	n/r	n/r	n/a (n/a n/a)	n/a	n/a (n/a n/a)

Positive values (+) indicate extension intervertebral endplate angles. Negative values (-) indicate flexion intervertebral endplate angles.

SAGITTAL ALIGNMENT DATA <sup>13</sup>					
PI	- L	L =	<b>-1°</b>		

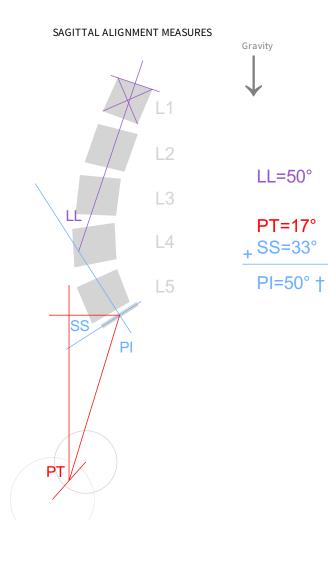
KEY: \Lambda Potential sagittal alignment issue

PI = pelvic incidence. PT = pelvic tilt. SS = sacral slope. LL = lumbar lordosis.

\*NOTE: The letters '**FN**' appearing within these alert icons indicates an alert that was triggered only in the device assisted bending images. If only uncontrolled bending images had been consulted, a potential "false negative" result for the underlying anomaly would have occurred.

<sup>+</sup> Pelvic Incidence calculated prior to rounding Sacral Slope and Pelvic Tilt. Apparent discrepancies due to rounding of intermediate values for presentation in this report.

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# VMA<sup>™</sup> Report Lumbar Translation Summary

#### PATIENT: Spondy, Steve PATIENT ID: 1563124 DOB: 03/03/1982 STUDY DATE: 6/21/2016 IMAGING EVENT ID: 58010 ACCESSION No: 19820303 PRESCRIBING PHYSICIAN: G Malcolmson, OKI\_Admin\_MD TEST CENTER: Statera Spine Demo

	TRANSLATION <sup>14</sup> DURING CONTROLLED BENDING							TRANSLATION <sup>3</sup>	<sup>4</sup> DURING UNCONTRO	LED BENDING	
	NEUTRAL	FLEXION	EXTENSION	NEUTRAL	LYING	EXTENSION	NEUTRAL	FLEXION	EXTENSION	LYING NE	PRONE
L1/L2	-0.9 mm -3%	0.1 mm 0%	-1.8 mm -5%	-2.1 mm -6%	-0.4 mm -1%	-2.2 mm -7%	2.3 mm 7%	-0.4 mm -1%	-1.9 mm -6%	n/r	n/r
L2/L3	-2.8 mm -8%	0.1 mm 0%	- <b>2.8</b> mm -8%	-1.1 mm -3%	1.1 mm 3%	-1.9 mm -6%	-2.7 mm -8%	-1.0 mm -3%	-2.0 mm -6%	n/r	n/r
L3/L4	-3.3 mm -9%	-0.6 mm -2%	<b>-2.7</b> mm -8%	-2.2 mm -6%	-1.3 mm -4%	- <b>1.9</b> mm -5%	- <b>2.0</b> mm -6%	-0.8 mm -2%	-2.7 mm -8%	n/r	n/r
L4/L5	-3.7 mm -10%	-3.1 mm -8%	-3.7 mm -10%	-2.4 mm -6%	-1.3 mm -4%	-0.8 mm -2%	-2.9 mm -8%	<b>-2.9</b> mm -8%	-3.0 mm -9%	-3.1 mm -9%	n/r
L5/S1	<sup>5.5</sup> mm <sup>15%</sup>	∧ 7.4 mm 20%	<b>△</b> <sup>5.1</sup> mm <sub>14%</sub>	<b>△</b> 5.3 mm 14%	3.4 mm 9%	<b>△</b> 5.3 mm 14%	<b>△</b> <sup>4.5</sup> mm 13%	<b>△</b> <sup>7.5</sup> mm 20%	n/r	<b>△</b> <sup>4.8</sup> mm 14%	n/r
N/A	n/r	n/r	n/r	n/r	n/r	n/r	n/r	n/r	n/r	n/r	n/r

KEY: A Potential mal-alignment or excessive motion\*

Potential borderline mal-alignment Potential residual motion at a or excessive motion\*

A Potential sagittal alignment issue

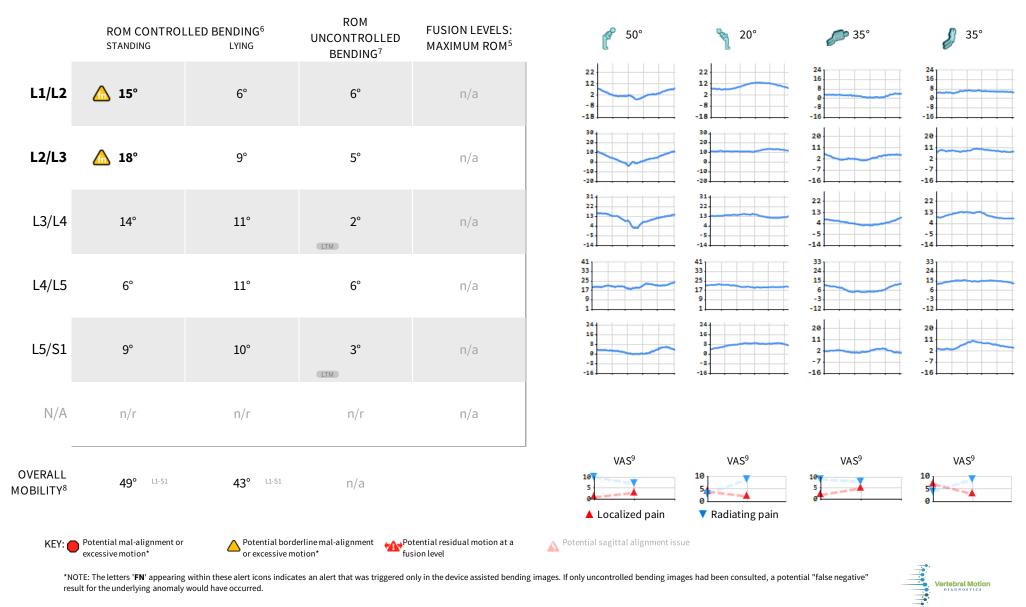
\*NOTE: The letters 'FN' appearing within these alert icons indicates an alert that was triggered only in the device assisted bending images. If only uncontrolled bending images had been consulted, a potential "false negative" result for the underlying anomaly would have occurred.

FIRST LETTER: Controlled (C) vs. Uncontrolled (U) bending. SECOND LETTER: Standing (S) vs. Lying (L) bending. THIRD LETTER: Flexion (F), Extension (E), Patient Left (L), Patient Right (R), or Neutral (N) view. XTP = Cross table prone. XTS = Cross table supine. LTM = Less than minimum motion threshold. See Quantitative Definitions page of this report package for further definition and reference thresholds. See Endnotes page for all footnotes.



# VMA<sup>™</sup> Report Lumbar Angulation (ROM) Flexion/Extension

PATIENT: Spondy, StevePATIENT ID: 1563124DOB: 03/03/1982STUDY DATE: 6/21/2016IMAGING EVENT ID: 58010ACCESSION No: 19820303PRESCRIBING PHYSICIAN: G Malcolmson, OKI\_Admin\_MDTEST CENTER: Statera Spine Demo



*FIRST LETTER*: Controlled (**C**) vs. Uncontrolled (**U**) bending. *SECOND LETTER*: Standing (**S**) vs. Lying (**L**) bending. *THIRD LETTER*: Flexion (**F**), Extension (**E**), Patient Left (**L**), Patient Right (**R**), or Neutral (**N**) view. **XTP** = Cross table prone. **XTS** = Cross table supine. **LTM** = Less than minimum motion threshold. See *Quantitative Definitions* page of this report package for further definition and reference thresholds. See *Endnotes* page for all footnotes.

VMA Version:

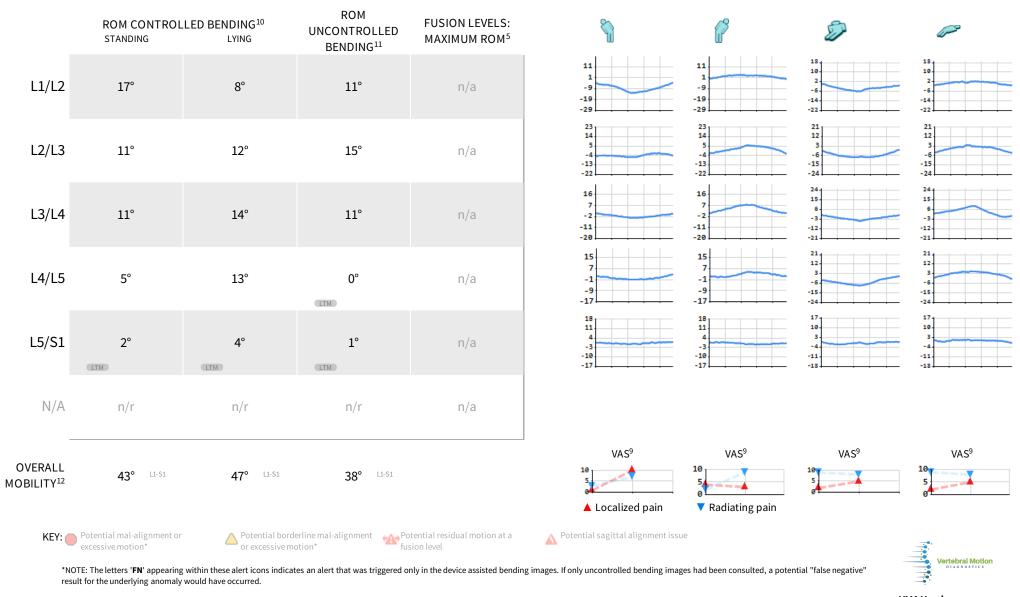
V 2.3.106 Report created on

3.0.296/3.0.45.0

8/8/2019 12:57:11 PM CST

# VMA<sup>™</sup> Report Lumbar Angulation (ROM) Left/Right

PATIENT: Spondy, StevePATIENT ID: 1563124DOB: 03/03/1982STUDY DATE: 6/21/2016IMAGING EVENT ID: 58010ACCESSION No: 19820303PRESCRIBING PHYSICIAN: G Malcolmson, OKI\_Admin\_MDTEST CENTER: Statera Spine Demo



*FIRST LETTER*: Controlled (C) vs. Uncontrolled (U) bending. *SECOND LETTER*: Standing (S) vs. Lying (L) bending. *THIRD LETTER*: Flexion (F), Extension (E), Patient Left (L), Patient Right (R), or Neutral (N) view. **XTP** = Cross table prone. **XTS** = Cross table supine. **LTM** = Less than minimum motion threshold. See *Quantitative Definitions* page of this report package for further definition and reference thresholds. See *Endnotes* page for all footnotes.

# VMA<sup>™</sup> Report Lumbar Alert Thresholds

#### PATIENT: **Spondy, Steve** PATIENT ID: **1563124** DOB: **03/03/1982** STUDY DATE: **6/21/2016** IMAGING EVENT ID: **58010** ACCESSION No: **19820303** PRESCRIBING PHYSICIAN: **G Malcolmson, OKI\_Admin\_MD** TEST CENTER: **Statera Spine Demo**

#### A. EXCESSIVE TRANSLATION BETWEEN VIEWS

	UNITS		NON-BORDERLINE
L1/L2	% mm	12 ≤X <14 4 ≤X <4.5	$\begin{array}{l} X \geq 14 \\ X \geq 4.5 \end{array}$
L2/L3	% mm	12 ≤X <13.5 4 ≤X <4.5	$\begin{array}{l} X \geq 13.5 \\ X \geq 4.5 \end{array}$
L3/L4	% mm	12 ≤X <13.5 4 ≤X <4.5	$\begin{array}{l} X \geq 13.5 \\ X \geq 4.5 \end{array}$
L4/L5	% mm	12 ≤X <13.5 4 ≤X <4.5	$\begin{array}{l} X \geq 13.5 \\ X \geq 4.5 \end{array}$
L5/S1	% mm	$12 \le X < 13.5$ $4 \le X < 4.5$	$\begin{array}{l} X \geq 13.5 \\ X \geq 4.5 \end{array}$

#### B. EXCESSIVE ANGULATION: MAXIMUM DIFFERENCE BETWEEN VIEWS

	UNITS		NON-BORDERLINE
L1/L2	Deg.	15° ≤X <22°	$X \ge 22^{\circ}$
L2/L3	Deg.	15° ≤X <22°	$X \ge 22^{\circ}$
L3/L4	Deg.	15° ≤X <22°	$X \ge 22^{\circ}$
L4/L5	Deg.	20° ≤X <22°	$X \ge 22^{\circ}$
L5/S1	Deg.	22° ≤X <26°	$X \ge 26^{\circ}$

#### C. MAL-ALIGNMENT\* (LISTHESIS)

	UNITS		NON-BORDERLINE
L1/L2	%	13 ≤X <25	25 ≤ X
	mm	4.4 ≤X <8.3	8.3 ≤ X
L2/L3	%	13 ≤X <25	25 ≤ X
LZ/LJ	mm	4.4 ≤X <8.3	8.3 ≤ X
L3/L4	%	13 ≤X <25	25 ≤ X
L3/L4	mm	4.4 ≤X <8.3	8.3 ≤ X
L4/L5	%	13 ≤X <25	25 ≤ X
L4/LJ	mm	4.4 ≤X <8.3	8.3 ≤ X
L5/S1	%	13 ≤X <25	25 ≤ X
LJ/ JI	mm	4.4 ≤X <8.3	8.3 ≤ X

#### D. MISCELLANEOUS ALERTS

THRESHOLD TYPE	ALERT LEVEL
🛆 EVIDENCE OF ABNORMAL Lumbar Sagittal Alignment	[Ref. range -10 to 10]
🕾 Residual Motion at Fused Level	ON
🙆 🛆 False Negative	ON
F. LESS THAN MINIMUM MOTION THRESHOLD (LTM) THRESHOLD TYPE	LTM THRESHOLD
Uncontrolled Angulation LTM (deg.)	x < 5°
Controlled Angulation LTM (deg.)	x < 5°
Subluxation LTM (%)	x < 5%
Instability LTM (%)	x < 5%

\*NOTE: Mal-alignment (listhesis) and excessive translation between views (instability) alerts are triggered if a patient's measure value exceeds either the mm or % value. % is percent of inferior vertebral body sagittal plane depth.

THRESHOLDS WERE CONFIGURED BY: G MALCOLMSON, OKI\_ADMIN\_MD



# VMA<sup>™</sup> Report Lumbar Report Endnotes

PATIENT: Spondy, StevePATIENT ID: 1563124DOB: 03/03/1982STUDY DATE: 6/21/2016IMAGING EVENT ID: 58010ACCESSION No: 19820303PRESCRIBING PHYSICIAN: G Malcolmson, OKI\_Admin\_MDTEST CENTER: Statera Spine Demo

Change Between Views values represent the maximum pairwise difference in translation for all image pairs possible within the set of up to 11 images (as shown on page), measured in the same millimeters and percent vertebral body depth units as described in (1) above. Subscripts refer to the specific view(s) from which the maximum translation values were observed (see KEY on page). Values are only returned for non-fusion levels and only for lateral-view images of flexion/extension bending (i.e. no measurements made from AP-view images of left/right bending).
Maximum angulation values are measured using the Frobin method (center plane of vertebral body) across all views, measured in degrees. Subscripts refer to the specific view(s) from which the maximum angulation values were observed (see KEY on page). Values are only returned for non-fusion levels.

4. Disc height is calculated according to the Frobin method and is measured in millimeters. Centerline disc height represents the average of the anterior and posterior disc heights.

5. For fusion levels, maximum confirmable angulation, measured in degrees, represents the maximum continuous angulation observed in any single cine imaging sequence, and may differ from the ROM values reported in other columns on this page.

6. Degrees of Intervertebral Range of Motion (angulation) observed between flexion and extension, taken from controlled, device-assisted lumbar bending. Values are only returned for nonfusion levels.

7. Degrees of Intervertebral Range of Motion (angulation) observed between flexion and extension, taken from uncontrolled patient lumbar bending. Values are only returned for non-fusion levels.

8. This is the sum of the L1-S1 motion, measured between the two end ranges (full flexion to full extension). Values are only provided if there are measurements at each level. Note that the sum of each level's angulation may be greater than the overall mobility, as overall mobility is measured between the two end ranges, while segmental mobility is measured as the maximum value observed at any point during the bend.

9. Visual Analog Scale (VAS) Pain scores were collected from patient during testing. Separate scores were collected for leg (below the belt) vs. back (above the belt) pain.

10. Degrees of Intervertebral Range of Motion (angulation) observed between left and right, taken from controlled patient lumbar bending. Values are only returned for non-fusion levels. 11. Degrees of Intervertebral Range of Motion (angulation) observed between left and right, taken from uncontrolled, device-assisted lumbar bending. Values are only returned for non-fusion levels. levels.

12. This is the sum of the L1-S1 motion, measured between the two end ranges (full left to full right). Values are only provided if there are measurements at each level. Note that the sum of each level's angulation may be greater than the overall mobility, as overall mobility is measured between the two end ranges, while segmental mobility is measured as the maximum value observed at any point during the bend.

The measurements of PI, SS, PT and LL come from an analysis of the lateral x-ray with the patient weight bearing in the neutral posture. The diagram is based on the same dataset.
Translation is measured using the Meyerding method, and provided in millimeter units [if possible], and also as percent of the inferior vertebral body sagittal-plane depth. Negative values refer to retrolisthesis, positive values refer to spondylolisthesis. Values are only returned for non-fusion levels and only for lateral-view images (e.g. flexion extension bending).
Lordosis Angle data table values are calculated as the angle between the inferior end plate of the cephalad vertebral body and the superior endplate of the caudal vertebral body.
Download IFU: https://portal.stateraspine.com/Mdportal/GetIFU

17. To order user manual, please contact Statera Spine at 512-334-5490 or compliance@stateraspine.com.



<sup>1.</sup> Maximum translation values In Any View are measured across all sagittal plane views. Translation is measured using the Meyerding method, and provided in millimeter units [if possible], and also as percent of the inferior vertebral body sagittal-plane depth. Negative values refer to retrolisthesis, positive values refer to spondylolisthesis. Subscripts may accompany these values, and when present refer to the specific view(s) from which the maximum translation values were observed (see KEY on page). Values are only returned for non-fusion levels and only for lateral-view images (i.e. only for flexion extension bending).

### Vertebral Motion Analysis<sup>™</sup> Lumbar Report



PATIENT: Jam, Jimmy PATIENT ID: 1563124 DOB: 03/03/1982 STUDY DATE: 6/21/2016 ACCESSION No: 19820303 PRESCRIBING PHYSICIAN: Demo, Doctor TEST CENTER: OKI Lab

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🔥 WARNING: When being viewed on a computer, a diagnostic-quality image review workstation should be used

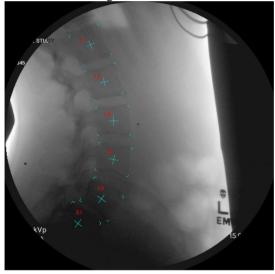
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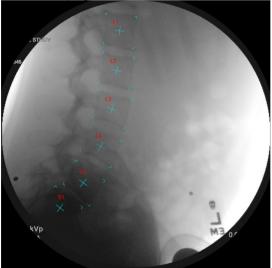
### (Standing & Lying) for Translation Measurements

PATIENT: Jam, Jimmy PATIENT ID: 1563124 DOB: 03/03/1982 STUDY DATE: 6/21/2016 ACCESSION No: 19820303 PRESCRIBING PHYSICIAN: Demo, Doctor TEST CENTER: OKI Lab

**Controlled Standing Lateral Neutral** 



Controlled Lying Lateral Neutral



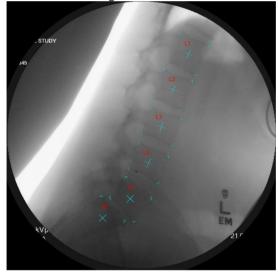
VMA Version: 2.3.1008/2.3.231.0 V 2.3.106 Report regenerated on 8/2/2016 2:23:18 PM CST



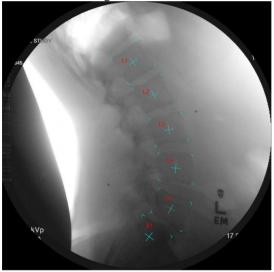
### (Standing & Lying) for Translation Measurements

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**Controlled Standing Flexion** 



Controlled Standing Extension



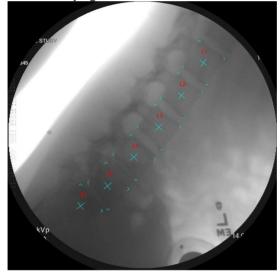
VMA Version: 2.3.1008/2.3.231.0 V 2.3.106 Report regenerated on 8/2/2016 2:23:21 PM CST



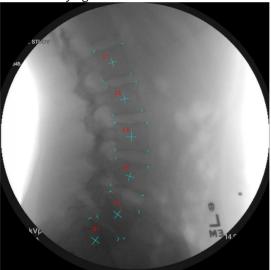
### (Standing & Lying) for Translation Measurements

PATIENT: Jam, Jimmy PATIENT ID: 1563124 DOB: 03/03/1982 STUDY DATE: 6/21/2016 ACCESSION No: 19820303 PRESCRIBING PHYSICIAN: Demo, Doctor TEST CENTER: OKI Lab

**Controlled Lying Flexion** 



**Controlled Lying Extension** 

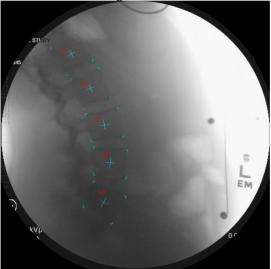


VMA Version: 2.3.1008/2.3.231.0 V 2.3.106 Report regenerated on 8/2/2016 2:23:23 PM CST

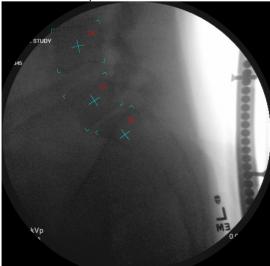
### (Standing & Lying) for Translation Measurements

PATIENT: Jam, Jimmy PATIENT ID: 1563124 DOB: 03/03/1982 STUDY DATE: 6/21/2016 ACCESSION No: 19820303 PRESCRIBING PHYSICIAN: Demo, Doctor TEST CENTER: OKI Lab

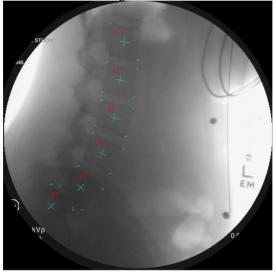
**Uncontrolled Standing Extension** 



Uncontrolled Supine Cross-table Lateral



**Uncontrolled Standing Flexion** 



VMA Version: 2.3.1008/2.3.231.0 V 2.3.106 Report regenerated on 8/2/2016 2:23:25 PM CST

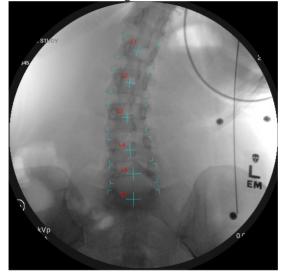
Vertebral Motion



### (Standing & Lying) for Translation Measurements

PATIENT: Jam, Jimmy PATIENT ID: 1563124 DOB: 03/03/1982 STUDY DATE: 6/21/2016 ACCESSION No: 19820303 PRESCRIBING PHYSICIAN: Demo, Doctor TEST CENTER: OKI Lab

Uncontrolled Standing Left



Uncontrolled Standing Right



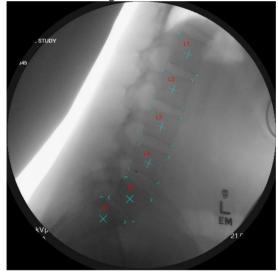
VMA Version: 2.3.1008/2.3.231.0 V 2.3.106 Report regenerated on 8/2/2016 2:23:27 PM CST



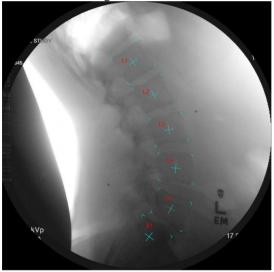
### (Standing & Lying) for Translation Measurements

PATIENT: Jam, Jimmy PATIENT ID: 1563124 DOB: 03/03/1982 STUDY DATE: 6/21/2016 ACCESSION No: 19820303 PRESCRIBING PHYSICIAN: Demo, Doctor TEST CENTER: OKI Lab

**Controlled Standing Flexion** 



Controlled Standing Extension



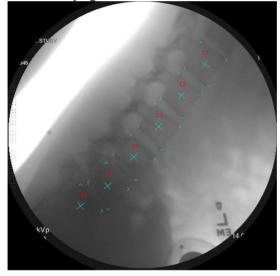
VMA Version: 2.3.1008/2.3.231.0 V 2.3.106 Report regenerated on 8/2/2016 2:23:29 PM CST



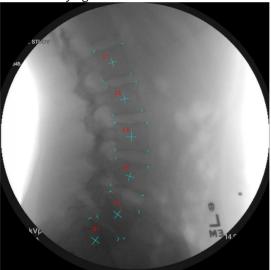
### (Standing & Lying) for Translation Measurements

PATIENT: Jam, Jimmy PATIENT ID: 1563124 DOB: 03/03/1982 STUDY DATE: 6/21/2016 ACCESSION No: 19820303 PRESCRIBING PHYSICIAN: Demo, Doctor TEST CENTER: OKI Lab

**Controlled Lying Flexion** 



**Controlled Lying Extension** 



VMA Version: 2.3.1008/2.3.231.0 V 2.3.106 Report regenerated on 8/2/2016 2:23:31 PM CST



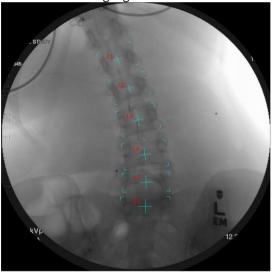
(Standing & Lying) for Translation Measurements

PATIENT: Jam, Jimmy PATIENT ID: 1563124 DOB: 03/03/1982 STUDY DATE: 6/21/2016 ACCESSION No: 19820303 PRESCRIBING PHYSICIAN: Demo, Doctor TEST CENTER: OKI Lab

**Controlled Standing Left** 



Controlled Standing Right



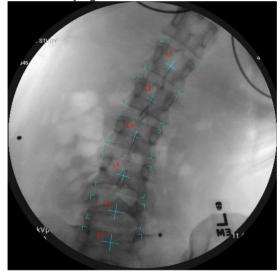
VMA Version: 2.3.1008/2.3.231.0 V 2.3.106 Report regenerated on 8/2/2016 2:23:32 PM CST



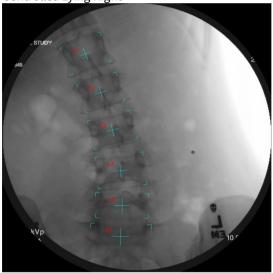
(Standing & Lying) for Translation Measurements

PATIENT: Jam, Jimmy PATIENT ID: 1563124 DOB: 03/03/1982 STUDY DATE: 6/21/2016 ACCESSION No: 19820303 PRESCRIBING PHYSICIAN: Demo, Doctor TEST CENTER: OKI Lab

**Controlled Lying Left** 



**Controlled Lying Right** 



VMA Version: 2.3.1008/2.3.231.0 V 2.3.106 Report regenerated on 8/2/2016 2:23:34 PM CST

### VMA<sup>™</sup> Report Sagittal Alignment Uploaded Images

Vertebral Motion Diagnostics

PATIENT: Jam, Jimmy PATIENT ID: 1563124 DOB: 03/03/1982 STUDY DATE: 6/21/2016 ACCESSION No: 19820303 PRESCRIBING PHYSICIAN: Demo, Doctor TEST CENTER: OKI Lab

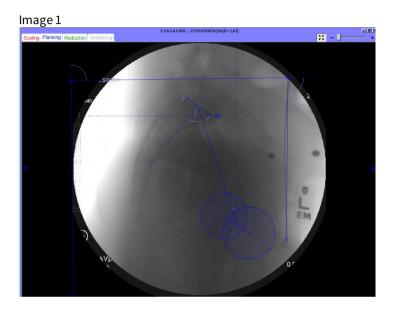


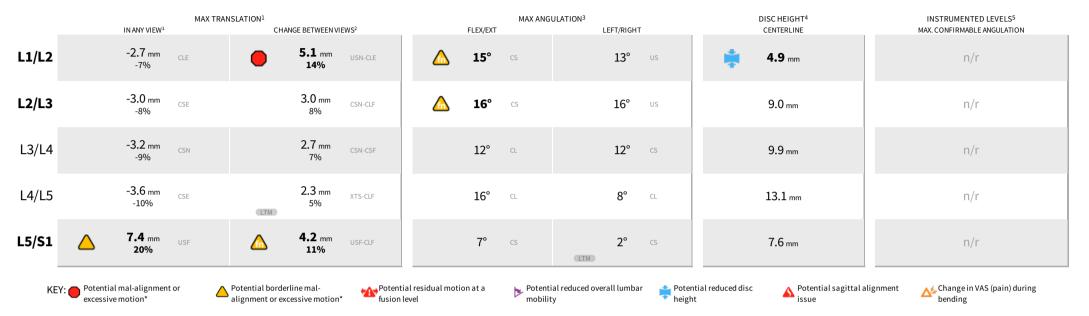
Image 2



VMA Version: 2.3.1008/2.3.231.0 V 2.3.106 Report regenerated on 8/2/2016 2:23:35 PM CST

### VMA<sup>™</sup> Report Lumbar Motion Analysis Summary

PATIENT: Jam, Jimmy PATIENT ID: 1563124 DOB: 03/03/1982 STUDY DATE: 6/21/2016 ACCESSION No: 19820303 PRESCRIBING PHYSICIAN: Demo, Doctor TEST CENTER: OKI Lab



\*NOTE: The letters 'FN' appearing within these alert icons indicates an alert that was triggered only in the device assisted bending images. If only uncontrolled bending images had been consulted, a potential "false negative" result for the underlying anomaly would have occurred.



### VMA<sup>™</sup> Report Lumbar Sagittal Alignment

PATIENT: Jam, JimmyPATIENT ID: 1563124DOB: 03/03/1982STUDY DATE: 6/21/2016ACCESSION No: 19820303PRESCRIBING PHYSICIAN: Demo, DoctorTEST CENTER: OKI Lab

	MAX. FLEX*	ORDOSIS ANGLE <sup>15</sup> STANDING NEUTRAL	, MAX. EXT*	ANTERIOR	DISC HEIGHT <sup>4</sup> CENTERLINE	POSTERIOR
L1/L2	-3°	8°	N/R	7.3 mm	📫 4.9 mm	<b>3.4</b> mm
L2/L3	-2°	10°	13°	12.3 mm	9.0 mm	5.9 mm
L3/L4	1°	11°	14°	13.7 mm	9.9 mm	6.2 mm
L4/L5	0°	16°	22°	18.4 mm	13.1 mm	8.0 mm
L5/S1	-3°	0°	4°	7.8 mm	7.6 mm	7.4 mm

SAGITTAL ALIGNMENT DATA <sup>13</sup>
$PI - LL = 4^{\circ}$

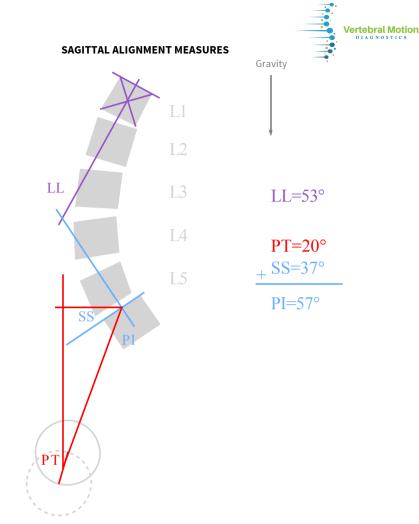
KEY: Potential reduced disc height

A Potential sagittal alignment issue

PI = pelvic incidence. PT = pelvic tilt. SS = sacral slope. LL = lumbar lordosis.

\*NOTE: The letters '**FN**' appearing within these alert icons indicates an alert that was triggered only in the device assisted bending images. If only uncontrolled bending images had been consulted, a potential "false negative" result for the underlying anomaly would have occurred.

Positive values (+) indicate extension intervertebral endplate angles. Negative values (-) indicate flexion intervertebral endplate angles.



### VMA<sup>™</sup> Report Lumbar Translation Summary



PATIENT: Jam, Jimmy PATIENT ID: 1563124 DOB: 03/03/1982 STUDY DATE: 6/21/2016 ACCESSION No: 19820303 PRESCRIBING PHYSICIAN: Demo, Doctor TEST CENTER: OKI Lab

TRANSLATION <sup>14</sup> DURING CONTROLLED BENDING					TRANSLATIO	N <sup>14</sup> DURING UNCONTRO	LED BENDING				
ſ		STANDING		1	LYING		7	STANDING		LYING N	EUTRAL
	NEUTRAL	FLEXION	EXTENSION	NEUTRAL	FLEXION	EXTENSION	NEUTRAL	FLEXION	EXTENSION	SUPINE	PRONE
.1/L2	-1.0 mm -3%	-0.1 mm 0%	<b>-2.0</b> mm -5%	-2.2 mm -6%	-0.3 mm -1%	- <b>2.7</b> mm -7%	<b>2.4</b> mm 7%	-0.4 mm -1%	<b>-2.3</b> mm -6%	n/a	n/a
2/L3	-3.0 mm -8%	-0.1 mm 0%	-3.0 mm -8%	-1.2 mm -3%	0.0 mm 0%	-2.1 mm -6%	-2.9 mm -8%	-1.0 mm -3%	-2.0 mm -6%	n/a	n/a
3/L4	-3.2 mm -9%	-0.5 mm -2%	-3.0 mm -8%	-2.1 mm -6%	-1.4 mm -4%	-3.0 mm -9%	-2.0 mm -6%	-0.8 mm -2%	-2.9 mm -8%	n/a	n/a
4/L5	-3.6 mm -10%	-3.1 mm -8%	- <b>3.6</b> mm -10%	-2.1 mm -6%	-1.3 mm -4%	-2.9 mm -8%	-2.8 mm -8%	-3.1 mm -8%	-3.5 mm -9%	-3.6 mm -9%	n/a
5/S1	△ 5.2 mm 14%	<sup>7.4</sup> mm <sup>20%</sup>	△ 4.8 mm 13%	△ 5.1 mm 14%	3.2 mm 9%	△ 4.7 mm 13%	▲ 4.5 mm 12%	<b>△</b> <sup>7.4</sup> mm 20%	n/a	<b>△</b> <sup>5.2</sup> <sub>14%</sub>	n/a

\*NOTE: The letters 'FN' appearing within these alert icons indicates an alert that was triggered only in the device assisted bending images. If only uncontrolled bending images had been consulted, a potential "false negative" result for the underlying anomaly would have occurred.

# VMA<sup>™</sup> Report Lumbar Angulation (ROM) Flexion/Extension



PATIENT: Jam, Jimmy PATIENT ID: 1563124 DOB: 03/03/1982 STUDY DATE: 6/21/2016 ACCESSION No: 19820303 PRESCRIBING PHYSICIAN: Demo, Doctor TEST CENTER: OKI Lab



\*NOTE: The letters 'FN' appearing within these alert icons indicates an alert that was triggered only in the device assisted bending images. If only uncontrolled bending images had been consulted, a potential "false negative" result for the underlying anomaly would have occurred.

# VMA<sup>™</sup> Report Lumbar Angulation (ROM) Left/Right



PATIENT: Jam, Jimmy PATIENT ID: 1563124 DOB: 03/03/1982 STUDY DATE: 6/21/2016 ACCESSION No: 19820303 PRESCRIBING PHYSICIAN: Demo, Doctor TEST CENTER: OKI Lab



\*NOTE: The letters 'FN' appearing within these alert icons indicates an alert that was triggered only in the device assisted bending images. If only uncontrolled bending images had been consulted, a potential "false negative" result for the underlying anomaly would have occurred.

### VMA<sup>™</sup> Report Lumbar Alert Thresholds



PATIENT: Jam, Jimmy PATIENT ID: 1563124 DOB: 03/03/1982 STUDY DATE: 6/21/2016 ACCESSION No: 19820303 PRESCRIBING PHYSICIAN: Demo, Doctor TEST CENTER: OKI Lab

#### A. EXCESSIVE TRANSLATION BETWEEN VIEWS

	UNITS		NON-BORDERLINE
L1/L2	% mm	$12 \le X < 13.5$ $4 \le X < 4.5$	$\begin{array}{l} X \geq 13.5 \\ X \geq 4.5 \end{array}$
L2/L3	% mm	$12 \le X < 13.5$ $4 \le X < 4.5$	$\begin{array}{l} X \geq 13.5 \\ X \geq 4.5 \end{array}$
L3/L4	% mm	12 ≤X <13.5 4 ≤X <4.5	$\begin{array}{l} X \geq 13.5 \\ X \geq 4.5 \end{array}$
L4/L5	% mm	12 ≤X <13.5 4 ≤X <4.5	$\begin{array}{l} X \geq 13.5 \\ X \geq 4.5 \end{array}$
L5/S1	% mm	12 ≤X <13.5 4 ≤X <4.5	$\begin{array}{l} X \geq 13.5 \\ X \geq 4.5 \end{array}$

#### B. EXCESSIVE ANGULATION: MAXIMUM DIFFERENCE BETWEEN VIEWS

	UNITS		NON-BORDERLINE
L1/L2	Deg.	15° ≤X <22°	$X \ge 22^{\circ}$
L2/L3	Deg.	15° ≤X <22°	$X \ge 22^{\circ}$
L3/L4	Deg.	15° ≤X <22°	$X \ge 22^{\circ}$
L4/L5	Deg.	20° ≤X <22°	$X \ge 22^{\circ}$
L5/S1	Deg.	22° ≤X <26°	$X \ge 26^{\circ}$

#### C. MAL-ALIGNMENT\* (LISTHESIS)

	UNITS		NON-BORDERLINE
L1/L2	%	13 ≤X <25	25 ≤ X
	mm	4.4 ≤X <8.3	8.3 ≤ X
L2/L3	%	13 ≤X <25	25 ≤ X
	mm	4.4 ≤X <8.3	8.3 ≤ X
L3/L4	%	13 ≤X <25	25 ≤ X
	mm	4.4 ≤X <8.3	8.3 ≤ X
L4/L5	%	13 ≤X <25	25 ≤ X
	mm	4.4 ≤X <8.3	8.3 ≤ X
L5/S1	%	13 ≤X <25	25 ≤ X
LJ/ J1	mm	4.4 ≤X <8.3	8.3 ≤ X

#### D. MISCELLANEOUS ALERTS

THRESHOLD TYPE	ALERT LEVEL
荣 Reduced Disc Height	5
▶ Reduced Range of Motion (L1/S1)	26
🛆 Sagittal Alignment (PI-LL)	10
🕸 Residual Motion at Fused Level	ON
🙆 🛆 False Negative Notification	ON
E. LUMBAR CHANGE IN PAIN (VAS)	
THRESHOLD TYPE	ALERT LEVEL
Local Pain Change Threshold	ΔVAS >4
Radiating Pain Change Threshold	ΔVAS >4
Alert requires Change in Both - Local <u>AND</u> Radiating Change in only one - Local <u>OR</u> Radiating	OR
Alert triggered when change in pain from Neutral Posture is <u>INCREASING, DECREASING</u> , or <u>BOTH</u>	Both
F. LESS THAN MINIMUM MOTION THRESHOLD (LTM)	
THRESHOLD TYPE	LTM THRESHOLD
Uncontrolled Angulation LTM (deg.)	x < 5°
Controlled Angulation LTM (deg.)	x < 5°
Subluxation LTM (%)	x < 5%
Instability LTM (%)	x < 5%

\*NOTE: Mal-alignment (listhesis) and excessive translation between views (instability) alerts are triggered if a patient's measure value exceeds either the mm or % value. % is percent of inferior vertebral body sagittal plane depth.

THRESHOLDS WERE CONFIGURED BY: DEMO, DOCTOR

# VMA<sup>™</sup> Report Lumbar Report Endnotes



PATIENT: Jam, Jimmy PATIENT ID: 1563124 DOB: 03/03/1982 STUDY DATE: 6/21/2016 ACCESSION No: 19820303 PRESCRIBING PHYSICIAN: Demo, Doctor TEST CENTER: OKI Lab

3. Maximum angulation values are measured using the Frobin method (center plane of vertebral body) across all views, measured in degrees. Subscripts refer to the specific view(s) from which the maximum angulation values were observed (see KEY on page). Values are only returned for non-fusion levels.

4. Disc height is calculated according to the Frobin method and is measured in millimeters. Centerline disc height represents the average of the anterior and posterior disc heights.

5. For fusion levels, maximum confirmable angulation, measured in degrees, represents the maximum continuous angulation observed in any single cine imaging sequence, and may differ from the ROM values reported in other columns on this page.

6. Degrees of Intervertebral Range of Motion (angulation) observed between flexion and extension, taken from controlled, device-assisted lumbar bending. Values are only returned for non-fusion levels.

7. Degrees of Intervertebral Range of Motion (angulation) observed between flexion and extension, taken from uncontrolled patient lumbar bending. Values are only returned for non-fusion levels.

8. This is the sum of the L1-S1 motion, measured between the two end ranges (full flexion to full extension). Values are only provided if there are measurements at each level. Note that the sum of each level's angulation may be greater than the overall mobility, as overall mobility is measured between the two end ranges, while segmental mobility is measured as the maximum value observed at any point during the bend.

9. Visual Analog Scale (VAS) Pain scores were collected from patient during testing. Separate scores were collected for leg (below the belt) vs. back (above the belt) pain.

10. Degrees of Intervertebral Range of Motion (angulation) observed between left and right, taken from controlled patient lumbar bending. Values are only returned for non-fusion levels.

11. Degrees of Intervertebral Range of Motion (angulation) observed between left and right, taken from uncontrolled, device-assisted lumbar bending. Values are only returned for non-fusion levels.

12. This is the sum of the L1-S1 motion, measured between the two end ranges (full left to full right). Values are only provided if there are measurements at each level. Note that the sum of each level's angulation may be greater than the overall mobility, as overall mobility is measured between the two end ranges, while segmental mobility is measured as the maximum value observed at any point during the bend. 13. The measurements of PI, SS, PT, and LL come from an analysis of images using OrthoView software (K063327). The diagram of sagittal alignment is rendered based on a dataset including data derived via the OrthoView as well as the VMA software.

14. Translation is measured using the Meyerding method, and provided in millimeter units [if possible], and also as percent of the inferior vertebral body sagittal-plane depth. Negative values refer to retrolisthesis, positive values refer to spondylolisthesis. Values are only returned for non-fusion levels and only for lateral-view images (e.g. flexion extension bending).

15. Lordosis Angle data table values are calculated as the angle between the inferior end plate of the cephalad vertebral body and the superior endplate of the caudal vertebral body.

Maximum translation values In Any View are measured across all sagittal plane views. Translation is measured using the Meyerding method, and provided in millimeter units [if possible], and also as percent of the inferior vertebral body sagittal-plane depth. Negative values refer to retrolisthesis, positive values refer to spondylolisthesis. Subscripts may accompany these values, and when present refer to the specific view(s) from which the maximum translation values were observed (see KEY on page). Values are only returned for non-fusion levels and only for lateral-view images (i.e. only for flexion extension bending).
Change Between Views values represent the maximum pairwise difference in translation for all image pairs possible within the set of up to 11 images (as shown on page), measured in the same millimeters and percent vertebral body depth units as described in (1) above. Subscripts refer to the specific view(s) from which the maximum translation values are only returned for non-fusion levels and only for lateral-view images of flexion/extension bending (i.e. no measurements made from AP-view images of left/right bending).

### Vertebral Motion Analysis<sup>™</sup> Cervical Report



PATIENT: **Pre-To-Post #2, Post-Op** PATIENT ID: **2346** DOB: **09/09/1978** STUDY DATE: **9/29/2019** IMAGING EVENT ID: **58007** ACCESSION No: **2346** PRESCRIBING PHYSICIAN: **Demo, Statera** TEST CENTER: **Statera Spine Demo** 

### **INDEX OF RESULTS**

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Cervical Motion Analysis Summary	2
Cervical Translation Summary	
Cervical Angulation (ROM): Flexion/Extension	4
Cervical Alert Thresholds	5
Cervical Report Endnotes	6

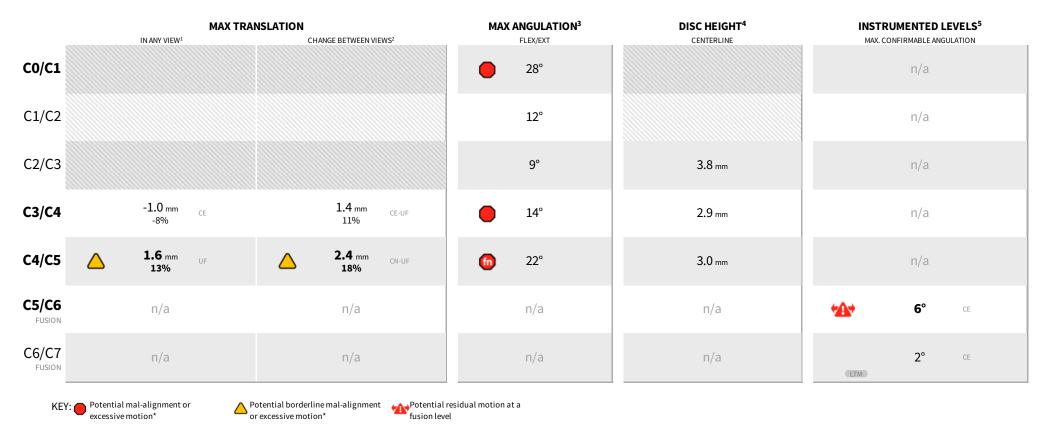
A WARNING: Inadequate tracking of vertebral bodies across radiographic images can lead to erroneous results. Image data and template placement must be reviewed prior to accepting any measurement results. If any templates are found to be incorrectly placed on vertebral bodies, any associated measurements should not be utilized in clinical decision making.

🔼 WARNING: When being viewed on a computer, a diagnostic-quality image review workstation should be used

VMA Version: 3.0.296/3.1.4.0 | V 2.2.101 Report created on 6/16/2022 12:19:27 PM CST (C) 2022

# VMA<sup>™</sup> Report Cervical Motion Analysis Summary

PATIENT: **Pre-To-Post #2, Post-Op** PATIENT ID: **2346** DOB: **09/09/1978** STUDY DATE: **9/29/2019** IMAGING EVENT ID: **58007** ACCESSION No: **2346** PRESCRIBING PHYSICIAN: **Demo, Statera** TEST CENTER: **Statera Spine Demo** 



\*NOTE: The letters 'FN' appearing within these alert icons indicates an alert that was triggered only in the device assisted bending images. If only uncontrolled bending images had been consulted, a potential "false negative" result for the underlying anomaly would have occurred.

*FIRST LETTER*: Controlled (**C**) vs. Uncontrolled (**U**) bending. second letter: Standing (**S**) vs. Lying (L) bending. third letter: Flexion (**F**), Extension (**E**), Patient Left (**L**), Patient Right (**R**), or Neutral (**N**) view. **XTP** = Cross table prone. **XTS** = Cross table supine. **LTM** = Less than minimum motion threshold. See *Quantitative Definitions* page of this report package for further definition and reference thresholds. See *Endnotes* page for all footnotes.



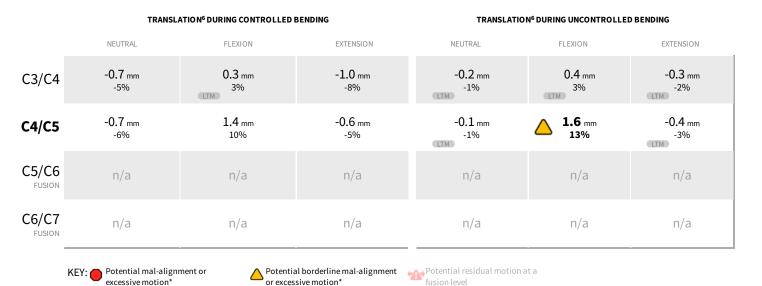
PATIENT LEVEL ALERTS:

NONE

# VMA<sup>™</sup> Report Cervical Translation Summary



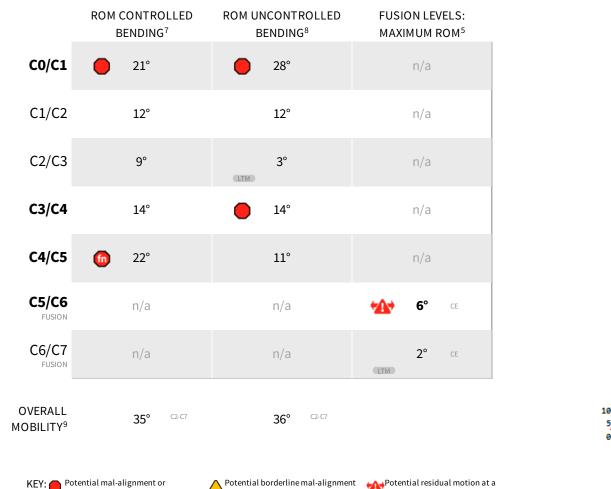
PATIENT: Pre-To-Post #2, Post-Op PATIENT ID: 2346 DOB: 09/09/1978 STUDY DATE: 9/29/2019 IMAGING EVENT ID: 58007 ACCESSION No: 2346 PRESCRIBING PHYSICIAN: Demo, Statera TEST CENTER: Statera Spine Demo



\*NOTE: The letters 'FN' appearing within these alert icons indicates an alert that was triggered only in the device assisted bending images. If only uncontrolled bending images had been consulted, a potential "false negative" result for the underlying anomaly would have occurred.

#### VMA<sup>™</sup> Report Cervical Angulation (ROM) Flexion/Extens **Vertebral Motion** DIAGNOSTICS

PATIENT: Pre-To-Post #2, Post-Op PATIENT ID: 2346 DOB: 09/09/1978 STUDY DATE: 9/29/2019 IMAGING EVENT ID: 58007 ACCESSION No: 2346 PRESCRIBING PHYSICIAN: Demo, Statera TEST CENTER: Statera Spine Demo



VAS<sup>10</sup> 10 Localized pain Radiating pain

45°

-23

26 10

VAS<sup>10</sup>

45°

Notential residual motion at a Potential borderline mal-alignment fusion level excessive motion\* or excessive motion\*

\*NOTE: The letters 'FN' appearing within these alert icons indicates an alert that was triggered only in the device assisted bending images. If only uncontrolled bending images had been consulted, a potential "false negative" result for the underlying anomaly would have occurred.

FIRST LETTER: Controlled (C) vs. Uncontrolled (U) bending. SECOND LETTER: (S) vs. Lying (L) bending. THIRD LETTER: Flexion (F), Extension (E), Patient Left (L), Patient Right (R), or Neutral (N) view. XTP = Cross table prone. XTS = Cross table supine. LTM = Less than minimum motion threshold. See Quantitative Definitions page of this report package for further definition and reference thresholds. See Endnotes page for all footnotes.

> VMA Version: 3.0.296/3.1.4.0 | V 2.2.101 Report created on 6/16/2022 12:19:21 PM CST (C) 2022

# VMA<sup>™</sup> Report Cervical Alert Thresholds



### PATIENT: **Pre-To-Post #2, Post-Op** PATIENT ID: **2346** DOB: **09/09/1978** STUDY DATE: **9/29/2019** IMAGING EVENT ID: **58007** ACCESSION No: **2346** PRESCRIBING PHYSICIAN: **Demo, Statera** TEST CENTER: **Statera Spine Demo**

#### A. EXCESSIVE TRANSLATION BETWEEN VIEWS

	UNITS		NON-BORDERLINE
C3/C4	% mm	12 ≤X <22 2 ≤X <3.5	$\begin{array}{c} X \geq 22 \\ X \geq 3.5 \end{array}$
C4/C5	% mm	12 ≤X <22 2 ≤X <3.5	$\begin{array}{c} X \geq 22 \\ X \geq 3.5 \end{array}$
C5/C6	% mm	12 ≤X <22 2 ≤X <3.5	$\begin{array}{c} X \geq 22 \\ X \geq 3.5 \end{array}$
C6/C7	% mm	$12 \le X < 22$ $2 \le X < 3.5$	$\begin{array}{c} X \geq 22 \\ X \geq 3.5 \end{array}$

#### **B. EXCESSIVE ANGULATION: MAXIMUM DIFFERENCE BETWEEN VIEWS**

	UNITS		NON-BORDERLINE
C0/C1	Deg.	7.9° ≤X <8°	$X \ge 8^{\circ}$
C1/C2	Deg.	10.9° ≤X <11°	$X \ge 11^{\circ}$
C2/C3	Deg.	10.9° ≤X <11°	$X \ge 11^{\circ}$
C3/C4	Deg.	10.9° ≤X <11°	$X \ge 11^{\circ}$
C4/C5	Deg.	10.9° ≤X <11°	$X \ge 11^{\circ}$
C5/C6	Deg.	10.9° ≤X <11°	$X \ge 11^{\circ}$
C6/C7	Deg.	10.9° ≤X <11°	$X \ge 11^{\circ}$

#### C. MAL-ALIGNMENT\* (SUBLUXATION)

	UNITS		NON-BORDERLINE
C3/C4	%	12 ≤X <22	22 ≤ X
CJ/ C4	mm	2 ≤X <3.5	3.5 ≤ X
C4/C5	%	12 ≤X <22	22 ≤ X
C4/C5	mm	2 ≤X <3.5	3.5 ≤ X
C5/C6	%	12 ≤X <22	22 ≤ X
CJ/C0	mm	2 ≤X <3.5	3.5 ≤ X
C6/C7	%	12 ≤X <22	22 ≤ X
C0/C1	mm	2 ≤X <3.5	3.5 ≤ X

#### D. MISCELLANEOUS ALERTS

THRESHOLD TYPE	ALERT LEVEL
殆 Residual Motion at Fused Level	ON
🝈 🛆 False Negative	ON

#### F. LESS THAN MINIMUM MOTION THRESHOLD (LTM)

THRESHOLD TYPE	LTM THRESHOLD
Uncontrolled Angulation LTM (deg.)	x < 5°
Controlled Angulation LTM (deg.)	x < 5°
Subluxation LTM (%)	x < 5%
Instability LTM (%)	x < 5%

\*NOTE: Mal-alignment (listhesis) and excessive translation between views (instability) alerts are triggered if a patient's measure value exceeds either the mm or % value. % is percent of inferior vertebral body sagittal plane depth.

#### THRESHOLDS WERE CONFIGURED BY: DEMO, STATERA

# VMA<sup>™</sup> Report Cervical Report Endnotes



PATIENT: Pre-To-Post #2, Post-Op PATIENT ID: 2346 DOB: 09/09/1978 STUDY DATE: 9/29/2019 IMAGING EVENT ID: 58007 ACCESSION No: 2346 PRESCRIBING PHYSICIAN: Demo, Statera TEST CENTER: Statera Spine Demo

Change Between Views values represent the maximum pairwise difference in translation for all image pairs possible within the set of up to 6 images (as shown on page), measured in the same millimeters and percent vertebral body depth units as described in (1) above. Subscripts refer to the specific view(s) from which the maximum translation values were observed (see KEY on page). Values are only returned for non-fusion levels and only for lateral-view images of flexion/extension bending (i.e. no measurements made from AP-view images of left/right bending).
Maximum angulation values are measured using the Frobin method (center plane of vertebral body) across all views, measured in degrees. Subscripts refer to the specific view(s) from which the maximum angulation values were observed (see KEY on page). Values are only returned for non-fusion levels.

4. Centerline disc height is calculated according to the Frobin method, is measured in millimeters, and represents the average of the anterior and posterior disc heights.

5. For fused levels, this is the maximum degrees of intervertebral angulation across the four device assisted bending directions. The icon depicts the specific bending mode in which the maximum angulation was observed. "n/a" is returned for all non-fusion levels.

6. Translation is measured using the Meyerding method, and provided in millimeter units (if possible). Translation is also provided as a percent of the inferior vertebral body sagittal-plane depth. Negative values refer to posterior subluxation of the superior vertebral body, positive values refer to anterior subluxation. Values are only returned for non-fusion levels.

7. Degrees of Intervertebral Range of Motion (angulation) observed between flexion and extension, taken from controlled, device-assisted cervical bending. Values are only returned for non-fusion levels.

8. Degrees of Intervertebral Range of Motion (angulation) observed between flexion and extension, taken from uncontrolled patient cervical bending. Values are only returned for non-fusion levels.

9. This is the sum of the C2-C6 or C2-C7 motion, measured between the two end ranges (full flexion to full extension). Values are only provided if there are measurements at each level. Note that the sum of each level's angulation may be greater than the overall mobility, as overall mobility is measured between the two end ranges, while segmental mobility is measured as the maximum value observed at any point during the bend.

10. Visual Analog Scale (VAS) Pain scores were collected from patient during testing. Separate scores were collected for neck (axial) vs. extremity (radiculopathy) pain.

11. Download IFU: https://portal.wenzelspine.com/Mdportal/GetIFU

12. To order user manual, please contact Wenzel Spine at (512) 469-0600 or compliance@wenzelspine.com.

VMA Version: 3.0.296/3.1.4.0 | V 2.2.101 Report created on 6/16/2022 12:19:21 PM CST (C) 2022

<sup>1.</sup> Maximum translation values In Any View are measured across all sagittal plane views. Translation is measured using the Meyerding method, and provided in millimeter units [if possible], and also as percent of the inferior vertebral body sagittal-plane depth. Negative values refer to posterior subluxation of the superior vertebral body, positive values refer to anterior subluxation. Subscripts may accompany these values, and when present refer to the specific view(s) from which the maximum translation values were observed (see KEY on page). Values are only returned for non-fusion levels and only for lateral-view images (i.e. flexion-extension bending).

### **Vertebral Motion Analysis**<sup>™</sup> XR Report



PATIENT: Way, Scott PATIENT ID: 001604514 DOB: 11/23/1971 STUDY DATE: 7/19/2019 IMAGING EVENT ID: 58889 ACCESSION No: 29692875 PRESCRIBING PHYSICIAN: G Malcolmson, OKI\_Admin\_MD TEST CENTER: Statera Spine Demo

### **INDEX OF RESULTS**

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Uncontrolled Bending End Range Lateral Views (Standing)	4

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A WARNING: Inadequate tracking of vertebral bodies across radiographic images can lead to erroneous results. Image data and template placement must be reviewed prior to accepting any measurement results. If any templates are found to be incorrectly placed on vertebral bodies, any associated measurements should not be utilized in clinical decision making. These images are provided in the front section of the printed report, prior to the quantitative data.

🔔 WARNING: When being viewed on a computer, a diagnostic-quality image review workstation should be used

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# VMA<sup>™</sup> Report **Uncontrolled Bending End Range AP Views** (Standing)

PATIENT: Way, Scott PATIENT ID: 001604514 DOB: 11/23/1971 STUDY DATE: 7/19/2019 IMAGING EVENT ID: 58889 ACCESSION No: 29692875 PRESCRIBING PHYSICIAN: G Malcolmson, OKI\_Admin\_MD TEST CENTER: Statera Spine Demo

#### Uncontrolled Standing A-P Neutral



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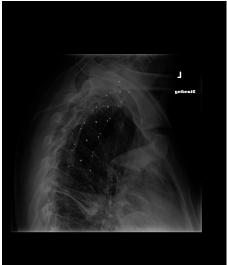
# VMA<sup>™</sup> Report **Uncontrolled Lateral Views**

PATIENT: Way, Scott PATIENT ID: 001604514 DOB: 11/23/1971 STUDY DATE: 7/19/2019 IMAGING EVENT ID: 58889 ACCESSION No: 29692875 PRESCRIBING PHYSICIAN: G Malcolmson, OKI\_Admin\_MD TEST CENTER: Statera Spine Demo

#### Uncontrolled XR



Uncontrolled XR



Uncontrolled XR



Uncontrolled XR



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Vertebral Motion

# VMA<sup>™</sup> Report **Uncontrolled Bending End Range Lateral Views** (Standing)

PATIENT: Way, Scott PATIENT ID: 001604514 DOB: 11/23/1971 STUDY DATE: 7/19/2019 IMAGING EVENT ID: 58889 ACCESSION No: 29692875 PRESCRIBING PHYSICIAN: G Malcolmson, OKI\_Admin\_MD TEST CENTER: Statera Spine Demo

#### **Uncontrolled Standing Flexion**



**Uncontrolled Standing Extension** 



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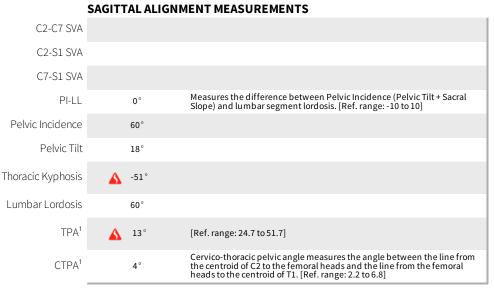
### **Statera Spine Demo**

110 Wild Basin Rd suite 250 Phone: (512) 334-5490



### Profile-ESP<sup>™</sup> Report Motion & Alignment

PATIENT: Way, Scott PATIENT ID: 001604514 DOB: 11/23/1971 STUDY DATE: 7/19/2019 IMAGING EVENT ID: 58889 ACCESSION NO: 29692875 PRESCRIBING PHYSICIAN: G Malcolmson, OKI\_Admin\_MD TEST CENTER: Statera Spine Demo



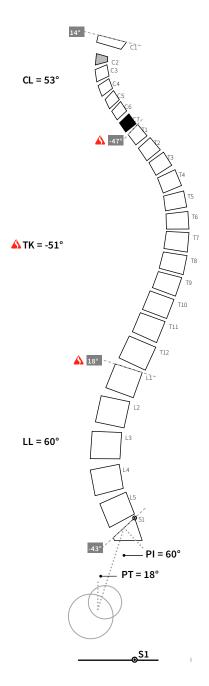
<sup>1</sup> TPA = Thoraco Pelvic Angle; CTPA = Cervical TPA

#### MOTION MEASUREMENTS

	Listhesis / Offset	Translation	Disc Height	Angulation F/E (ROM) <sup>2</sup>	Angulation L/R (ROM) <sup>2</sup>
L1/L2	-9%	N/R	N/R	14°	N/R
L2/L3	-8%	N/R	N/R	8°	N/R
L3/L4	-6%	N/R	N/R	2°	N/R
L4/L5	5 %	N/R	N/R	1°	N/R
L5/S1	-9 %	N/R	N/R	5°	N/R

 $^{2}$  ROM = Range of Motion; F/E = Flexion/Extension; L/R = Left/Right L/R bend ROM data is pulled from the Left and Right bend films only.

NOTES: L1-S1 Regional range of motion (bending range) = 28 deg.



▲ = Potential sagittal alignment issue

N/A = Not Applicable (no image data collected) N/R = No Result (no measurement was possible)

MEASUREMENT & REFERENCE RANGE DETAILS: <u>https://www.wenzelspine.com/xr-info</u> Download IFU: <u>https://portal.wenzelspine.com/Mdportal/GetIFU</u> VMA Version: 3.1.1/3.1.1.0 Report created on 4/1/2022 9:25:45 PM CST (C) 2022 Wenzel Spine, Inc 5 / 8

# VMA<sup>™</sup> Report Lumbar Alert Thresholds

#### PATIENT: Way, Scott PATIENT ID: 001604514 DOB: 11/23/1971 STUDY DATE: 7/19/2019 IMAGING EVENT ID: 58889 ACCESSION No: 29692875 PRESCRIBING PHYSICIAN: G Malcolmson, OKI\_Admin\_MD TEST CENTER: Statera Spine Demo

#### A. EXCESSIVE TRANSLATION BETWEEN VIEWS

	UNITS		NON-BORDERLINE
L1/L2	% mm	12 ≤X <14 4 ≤X <4.5	$\begin{array}{l} X \geq 14 \\ X \geq 4.5 \end{array}$
L2/L3	% mm	$12 \le X < 13.5$ $4 \le X < 4.5$	$\begin{array}{l} X \geq 13.5 \\ X \geq 4.5 \end{array}$
L3/L4	% mm	12 ≤X <13.5 4 ≤X <4.5	$\begin{array}{l} X \geq 13.5 \\ X \geq 4.5 \end{array}$
L4/L5	% mm	12 ≤X <13.5 4 ≤X <4.5	$\begin{array}{l} X \geq 13.5 \\ X \geq 4.5 \end{array}$
L5/S1	% mm	12 ≤X <13.5 4 ≤X <4.5	$\begin{array}{l} X \geq 13.5 \\ X \geq 4.5 \end{array}$

#### B. EXCESSIVE ANGULATION: MAXIMUM DIFFERENCE BETWEEN VIEWS

	UNITS		NON-BORDERLINE
L1/L2	Deg.	15° ≤X <22°	$X \ge 22^{\circ}$
L2/L3	Deg.	15° ≤X <22°	X ≥ 22°
L3/L4	Deg.	15° ≤X <22°	$X \ge 22^{\circ}$
L4/L5	Deg.	20° ≤X <22°	X ≥ 22°
L5/S1	Deg.	22° ≤X <26°	$X \ge 26^{\circ}$

#### C. MAL-ALIGNMENT\* (LISTHESIS)

	UNITS		NON-BORDERLINE
L1/L2	%	13 ≤X <25	25 ≤ X
	mm	4.4 ≤X <8.3	8.3 ≤ X
L2/L3	%	13 ≤X <25	25 ≤ X
LZ/LJ	mm	4.4 ≤X <8.3	8.3 ≤ X
L3/L4	%	13 ≤X <25	25 ≤ X
L3/L4	mm	4.4 ≤X <8.3	8.3 ≤ X
L4/L5	%	13 ≤X <25	25 ≤ X
L4/LJ	mm	4.4 ≤X <8.3	8.3 ≤ X
L5/S1	%	13 ≤X <25	25 ≤ X
LJ/ JI	mm	4.4 ≤X <8.3	8.3 ≤ X

#### D. MISCELLANEOUS ALERTS

THRESHOLD TYPE	ALERT LEVEL
殆 Residual Motion at Fused Level	ON
🙆 🛆 False Negative	ON
F. LESS THAN MINIMUM MOTION THRESHOLD (LTM)	
THRESHOLD TYPE	LTM THRESHOLD
Uncontrolled Angulation LTM (deg.)	x < 5°
Controlled Angulation LTM (deg.)	x < 5°
Subluxation LTM (%)	x < 5%
Instability LTM (%)	x < 5%

\*NOTE: Mal-alignment (listhesis) and excessive translation between views (instability) alerts are triggered if a patient's measure value exceeds either the mm or % value. % is percent of inferior vertebral body sagittal plane depth.

THRESHOLDS WERE CONFIGURED BY: G MALCOLMSON, OKI\_ADMIN\_MD



# VMA<sup>™</sup> Report XR Alert Thresholds

Vertebral Motion DIAGNOSTICS

PATIENT: Way, Scott PATIENT ID: 001604514 DOB: 11/23/1971 STUDY DATE: 7/19/2019 IMAGING EVENT ID: 58889 ACCESSION No: 29692875 PRESCRIBING PHYSICIAN: G Malcolmson, OKI\_Admin\_MD TEST CENTER: Statera Spine Demo

	UNITS	NON- BORDERLINE	NORMAL	NON- BORDERLINE
CL	Deg.	X≤	< X <	X ≥
LL	Deg.	X≤	< X <	X ≥
PT	Deg.	X≤	< X <	X ≥
PI	Deg.	X≤	< X <	X ≥
PI-LL	Deg.	X ≤ -10	-10 < X < 10	$X \ge 10$
C1 Slope	Deg.	X≤	< X <	X ≥
T1 Slope	Deg.	X ≤ -32.1	-32.1 < X < -19.3	X ≥ -19.3
L1 Slope	Deg.	X ≤ 3.5	3.5 < X < 13.5	X ≥ 13.5
S1 Slope	Deg.	X ≤ -51.3	-51.3 < X < -31.3	X ≥ -31.3
Thoraco-Pelvic Angle	Deg.	X ≤ 24.7	24.7 < X < 51.7	X ≥ 51.7
Cervico-Thoraco-Lumbar Pelvic Angle	Deg.	X ≤ 2.2	2.2 < X < 6.8	X ≥ 6.8
Thoracic Kyphosis	Deg.	X ≤ -43.2	-43.2 < X < -8.8	X ≥ -8.8
C2-C7 SVA	mm	$X \leq 11$	11 < X < 63	X ≥ 63
C2-S1 SVA	mm	X ≤ 8	8 < X < 40	X ≥ 40
C7-S1 SVA	mm	X ≤ -20	-20 < X < 20	X ≥ 20

\*NOTE: Mal-alignment (listhesis) and excessive translation between views (instability) alerts are triggered if a patient's measure value exceeds either the mm or % value. % is percent of inferior vertebral body sagittal plane depth.

THRESHOLDS WERE CONFIGURED BY: G MALCOLMSON, OKI\_ADMIN\_MD

# VMA<sup>™</sup> Report **XR Report Endnotes**



PATIENT: Way, Scott PATIENT ID: 001604514 DOB: 11/23/1971 STUDY DATE: 7/19/2019 IMAGING EVENT ID: 58889 ACCESSION NO: 29692875 PRESCRIBING PHYSICIAN: G Malcolmson, OKI\_Admin\_MD TEST CENTER: Statera Spine Demo

Change Between Views values represent the maximum pairwise difference in translation for all image pairs possible within the set of up to 11 images (as shown on page), measured in the same millimeters and percent vertebral body depth units as described in (1) above. Subscripts refer to the specific view(s) from which the maximum translation values were observed (see KEY on page). Values are only returned for non-fusion levels and only for lateral-view images of flexion/extension bending (i.e. no measurements made from AP-view images of left/right bending).
Maximum angulation values are measured using the Frobin method (center plane of vertebral body) across all views, measured in degrees. Subscripts refer to the specific view(s) from which the maximum angulation values were observed (see KEY on page). Values are only returned for non-fusion levels.

4. Disc height is calculated according to the Frobin method and is measured in millimeters. Centerline disc height represents the average of the anterior and posterior disc heights.

5. For fusion levels, maximum confirmable angulation, measured in degrees, represents the maximum continuous angulation observed in any single cine imaging sequence, and may differ from the ROM values reported in other columns on this page.

6. Degrees of Intervertebral Range of Motion (angulation) observed between flexion and extension, taken from controlled, device-assisted lumbar bending. Values are only returned for nonfusion levels.

7. Degrees of Intervertebral Range of Motion (angulation) observed between flexion and extension, taken from uncontrolled patient lumbar bending. Values are only returned for non-fusion levels.

8. This is the sum of the L1-S1 motion, measured between the two end ranges (full flexion to full extension). Values are only provided if there are measurements at each level. Note that the sum of each level's angulation may be greater than the overall mobility, as overall mobility is measured between the two end ranges, while segmental mobility is measured as the maximum value observed at any point during the bend.

9. Visual Analog Scale (VAS) Pain scores were collected from patient during testing. Separate scores were collected for leg (below the belt) vs. back (above the belt) pain.

10. Degrees of Intervertebral Range of Motion (angulation) observed between left and right, taken from controlled patient lumbar bending. Values are only returned for non-fusion levels. 11. Degrees of Intervertebral Range of Motion (angulation) observed between left and right, taken from uncontrolled, device-assisted lumbar bending. Values are only returned for non-fusion levels. levels.

12. This is the sum of the L1-S1 motion, measured between the two end ranges (full left to full right). Values are only provided if there are measurements at each level. Note that the sum of each level's angulation may be greater than the overall mobility, as overall mobility is measured between the two end ranges, while segmental mobility is measured as the maximum value observed at any point during the bend.

The measurements of PI, SS, PT and LL come from an analysis of the lateral x-ray with the patient weight bearing in the neutral posture. The diagram is based on the same dataset.
Translation is measured using the Meyerding method, and provided in millimeter units [if possible], and also as percent of the inferior vertebral body sagittal-plane depth. Negative values refer to retrolisthesis, positive values refer to spondylolisthesis. Values are only returned for non-fusion levels and only for lateral-view images (e.g. flexion extension bending).
Lordosis Angle data table values are calculated as the angle between the inferior end plate of the cephalad vertebral body and the superior endplate of the caudal vertebral body.
Download IFU: <a href="https://portal.wenzelspine.com/Mdportal/GetIFU">https://portal.wenzelspine.com/Mdportal/GetIFU</a>

17. To order user manual, please contact Wenzel Spine at (512) 469-0600 or compliance@wenzelspine.com.

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<sup>1.</sup> Maximum translation values In Any View are measured across all sagittal plane views. Translation is measured using the Meyerding method, and provided in millimeter units [if possible], and also as percent of the inferior vertebral body sagittal-plane depth. Negative values refer to retrolisthesis, positive values refer to spondylolisthesis. Subscripts may accompany these values, and when present refer to the specific view(s) from which the maximum translation values were observed (see KEY on page). Values are only returned for non-fusion levels and only for lateral-view images (i.e. only for flexion extension bending).

### DEMO

110 Wild Basin Rd suite 250 Austin, TX, 78746

#### Lumbar Motion X-ray Report :

Patient Name: Spondy,	Steve Study Date:
<b>DOB:</b> 03/03/1982	9/29/2019
MR Number: 1563124	Accession Number: 19820303
Prescriber: Demo, Statera	Image Event Id: 58010

#### Technique:

Radiologic interpretation is provided for images aggregated from two image sets. Seven views of the Lumbar spine and one view of the lateral pelvis were captured during patient free-bending, specifically three lateral plain views (flexion, extension, neutral) and three anterior/posterior plain views (neutral, bending to patient left, bending to patient right) and a lateral view of the pelvis including femoral heads. Live fluoroscopic cine imaging was additionally captured and recorded during a set of eight device-assisted Lumbar spine bending routines. A total dose of N/A was recorded for the fluoroscopic imaging.

#### Findings:

L1/L2: Max sagittal mal-alignment (listhesis): Does not exceed reference limits (-2.2 mm/ -7%) Max sagittal translation between views (instability): EVIDENCE OF INSTABILITY (EXCESSIVE TRANSLATION) (4.5 mm/ 14%) Max angulation between views: EVIDENCE OF BORDERLINE INSTABILITY (EXCESSIVE ANGULATION) (flex/ext: 15 degrees) Disc Height: (9.2 mm)

L2/L3: Max sagittal mal-alignment (listhesis): Does not exceed reference limits (-2.7 mm/-8%) Max sagittal translation between views (instability): Does not exceed reference limits (3.7 mm/11%) Max angulation between views: **EVIDENCE OF BORDERLINE INSTABILITY (EXCESSIVE ANGULATION)** (flex/ext: 18 degrees) Disc Height: (8.7 mm)

L3/L4: Max sagittal mal-alignment (listhesis): Does not exceed reference limits (-3.3 mm/ -9%) Max sagittal translation between views (instability): Does not exceed reference limits (2.8 mm/ 8%) Max angulation between views: Does not exceed reference limits (flex/ext: 14 degrees) Disc Height: (9.3 mm)

L4/L5: Max sagittal mal-alignment (listhesis): Does not exceed reference limits (-3.7 mm/-10%) Max sagittal translation between views (instability): Does not exceed reference limits (2.9 mm/8%) Max angulation between views: Does not exceed reference limits (flex/ext: 11 degrees) Disc Height: (12.3 mm)

L5/S1: Max sagittal mal-alignment (listhesis): EVIDENCE OF GRADE 1 ANTEROLISTHESIS (7.5 mm/ 20%) Max sagittal translation between views (instability): EVIDENCE OF BORDERLINE INSTABILITY (EXCESSIVE TRANSLATION) (4.1 mm / 11%) Max angulation between views: Does not exceed reference limits (flex/ext: 10 degrees) Disc Height: (7.2 mm)

Sagittal Alignment Data:  $PI-LL = -1^{\circ}$ LL = 50°; SS= 33°;  $PT= 17^{\circ}$ ;  $PI= 50^{\circ}$ 

Note: Reported motion values for a level represent the maximum of motion measured during any bend. Units of "%" refer to percent vertebral body



depth of the inferior adjacent vertebral body. LTM stands for Less Than Minimum motion in angulation.

#### Impression:

There is **INSTABILITY (EXCESSIVE TRANSLATION)** (4.5 mm/14%) at L1/L2. There is **BORDERLINE INSTABILITY (EXCESSIVE ANGULATION)** (15 degrees) at L1/L2.

There is **BORDERLINE INSTABILITY (EXCESSIVE ANGULATION)** (18 degrees) at L2/L3.

There is EVIDENCE OF GRADE 1 ANTEROLISTHESIS (7.5 mm/20%) at L5/S1 with EVIDENCE OF BORDERLINE INSTABILITY (EXCESSIVE TRANSLATION) at L5/S1 (4.1 mm/11%)

At all other imaged levels, no other motion anomalies were detected.

At all other imaged levels, no other motion anomalies were detected. The images in this study were exclusively analyzed for motion assessment and sagittal alignment of the lumbar spine. Radiographic assessment beyond this motion analysis was not performed.

Digitally Signed by: Statera Demo, on 02/22/2021 at 23:18 CST