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Urgent Field Safety Notice

UNiD™ Adaptive Spine Intelligence

Potential for Incorrect Surgical Parameters in the UNiD HUB

Notification

December 2024

Medtronic Reference: FA1444

EU Manufacturer Single Registration Number (SRN): FR-MF-000001866

Dear Healthcare Professional/Risk Manager,

The purpose of this notice is to inform you of software anomalies in the UNiD™ HUB that may have impacted UNiD rod planning. Specifically, certain optional surgical parameters, provided as reference during surgical planning, may have had errors that resulted in incorrect calculations displayed in the UNiD™ HUB, which is available within the UNiD™ Adaptive Spine Intelligence system. Relevant and impacted parameters are the following: *Roussouly Classification*, *Real Lumbar Lordosis* and *Real Thoracic Kyphosis*, *Barrey Ratio*, and *Lenke Classification*.

There have been no reports of serious patient injury; however, if miscalculated parameters were used to develop the surgical plan, the plan may be inadequate to address patient needs. Refer to Appendix B and Appendix C for images showing where these parameters might appear in the UNiD HUB and the UNiD Operation Room (O.R.) Case Memo.

Physicians who have been identified as a registered surgeon user ("Authorized User") on the UNiD HUB are receiving this notification.

Product and Issue Description:

The UNiD HUB is a cloud-based healthcare software application used to receive, transfer, display, and store data used for planning a spine surgery and/or for postoperative follow-up (patient information, X-ray image and recommendations for planning). The software anomalies may be displayed to surgeons in the UNiD HUB or the UNiD Operation Room (O.R.) Case Memo.

The four (4) anomalies which may result in potentially incorrect parameters are summarized below, and additional detail regarding the parameters is included in Appendix A. Each of these parameters may be used for planning of sagittal alignment and the intended rod curvature and length.

- **Roussouly Classification**
 - A parameter that defines the spinal curvature according to sacral slope (SS) and the spine curvature inflection point.
 - Potential for spinal curvature that should be identified as “type 2” to be misidentified as “type 1” or “type 3” due to use of incorrect inflection point in the measurement and calculation.
- **Real Lumbar Lordosis and Real Thoracic Kyphosis**
 - Measurements that describe spinal lordosis and kyphosis.
 - Potential for incorrect values to be presented due to use of incorrect inflection point in the measurement and calculation.
- **Barrey Ratio**
 - A calculation used to measure global sagittal alignment.
 - Potential for pre-op Barry Ratio to be incorrect due to image processing in the Analyzer.
- **Lenke Classification**
 - A parameter that defines the type of curve, the lumbar modifier and the sagittal modifier in order to categorize classification of adolescent idiopathic scoliosis (AIS).
 - Potential for the classification to not be adapted to the patient anatomy.

Potential Patient Risk:

Any of the four (4) of the described parameters, if miscalculated and leveraged to determine a surgical plan, have the potential to result in long-term impacts for patients, including suboptimal surgical plan and sagittal balance, potentially leading to a higher incidence of additional surgical intervention.

Real LL/Real TK miscalculations may result in surgical delay for modification of rod length or contour at the time of surgery.

Patient Management Recommendations:

If a UNiD rod was planned without any of these four parameters and met the surgeons planned surgical objectives, no additional actions are required. As these parameters are optional for planning, there is no record of whether the parameters were utilized for surgical planning. If you are concerned that the use of these parameters may have adversely impacted a patient's sagittal balance, it is recommended to re-evaluate the surgical plan and continue to follow the patient based on your assessment of their post operative sagittal balance. Monitor patients per routine standard of care and intervene per medical judgement.

Medtronic Actions:

Medtronic has released a software update as of December 3, 2024 that removes the impacted parameters: Roussouly Classification, Real LL/Real TK, Barrey Ratio and Lenke Classification from UNiD HUB. These parameters will no longer be available for use in future case plans.

Customer Actions:

- Please review this information within this letter
- Healthcare providers may continue to use the UNiD HUB as instructed in the External User Guide.
- Please confirm via the enclosed Customer Acknowledgement Form that this notification has been communicated within your facility with all physician users. Send the completed Customer Acknowledgement Form to Medtronic.
- This notice needs to be passed on to those who need to be aware within your organization that utilizes the UNiD HUB for planning. Please maintain a copy of this notice in your records.

Additional Information

Medtronic has notified the Competent Authority of your country of this action.

We regret any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter. If you have questions related to this issue, please contact your local Medtronic representative at 01 511 1400.

Sincerely,



Bethany Moxon

Associate Regulatory Affairs Specialist – UK and Ireland

Enclosures:

- Appendix A: Software Anomaly Descriptions
- Appendix B: Barrey Ratio, Real LL/Real TK, Roussouly Classification in the UNiD HUB
- Appendix C: Lenke Classification in the UNiD HUB and UNiD O.R. Case Memo Parameters
- Customer Acknowledgement Form

Appendix A -Software Anomaly Descriptions

Roussouly Classification

- **Roussouly Classification** is a spinal curvature parameter according to sacral slope (SS) and the spine curvature inflection point.¹ There are four Roussouly types:
 - Type 1 lordosis is characterized by $SS < 35^\circ$ and an inflection point (where the orientation of vertebral bodies changes) at L3/L4.
 - Type 2 lordosis is characterized by $SS < 35^\circ$ and an inflection point at L1/L2.
 - Type 3 lordosis is characterized by $35^\circ < SS < 45^\circ$ and an inflection point at T12/L1.
 - Type 4 lordosis is characterized by $SS > 45^\circ$ and an inflection point at T9/T10.
- The UNiD Spine Analyzer incorrectly calculates Roussouly Classification, specifically Roussouly Type 2. The Spine Analyzer uses the incorrect inflection point for its Roussouly classification and, consequently, Type 2 is incorrectly shown in the UNiD HUB as Type 1 or Type 3.
- Roussouly Classification is an optional planning parameter and was only displayed in the UNiD HUB when the corresponding box was checked under Spinopelvic Parameters (see Appendix B). The parameter has been potentially miscalculated since 05-Nov-2019.
- Medtronic has received one (1) customer complaint associated with the Roussouly Classification issue, which did not result in patient harm.

Real Lumbar Lordosis and Real Thoracic Kyphosis

- **Real Lumbar Lordosis** and **Real Thoracic Kyphosis** are alternatives to traditional Lumbar Lordosis and Thoracic Kyphosis measurements, which describe lordosis and kyphosis. The Lumbar Lordosis (LL) Angle is measured between the endplate of S1 and the superior endplate of L1, while **Real LL** is measured between the endplate of S1 and a vertical line from the spline on the inflection point of the lordosis. The Thoracic Kyphosis (TK) Angle is measured between the upper endplate of T4 to the lower endplate of T12, while **Real TK** is measured between a vertical line from the rod spline on the inflexion point of the lordosis and a vertical line from the spline on the inflection point of the kyphosis.²
- The UNiD Spine Analyzer uses the incorrect inflection point to calculate Real LL. Real TK is based on Real LL, so it is also incorrect.
- Real LL and Real TK are optional planning parameters and were only displayed in the UNiD HUB when the corresponding boxes were selected by the surgeon or Medtronic UNiD Lab Engineer under Spinopelvic Parameters (see Appendix B). The parameters have been potentially miscalculated since 05-Nov-2019.
- Medtronic detected this anomaly internally. Medtronic has not received any customer complaints associated with the Real LL/Real TK issue.

¹ Roussouly, Pierre, and Colin Nnadi. "Sagittal Plane Deformity: An Overview of Interpretation and Management." *European Spine Journal*, vol. 19, no. 11, Nov. 2010, pp. 1824–36. DOI.org (Crossref), <https://doi.org/10.1007/s00586-010-1476-9>.

² Clément, J.L., Pelletier, Y., Solla, F. *et al.* Surgical increase in thoracic kyphosis increases unfused lumbar lordosis in selective fusion for thoracic adolescent idiopathic scoliosis. *Eur Spine J* **28**, 581–589 (2019). <https://doi.org/10.1007/s00586-018-5740-8>

Barrey Ratio

- **Barrey Ratio** is the ratio between the sagittal vertical axis (SVA) and the distance between the posterosuperior corner of sacrum and the center of femoral heads.³ The Barrey ratio is used to measure global sagittal alignment.
- The UNiD Spine Analyzer incorrectly changes the pre-op Barrey Ratio value when the Medtronic UNiD Lab Engineer applies the predictive model and changes the pelvic tilt (PT). The final plan's Barrey ratio is accurate.
- Barrey Ratio is an optional planning parameter and was only displayed in the UNiD HUB when the corresponding box was checked under Spinopelvic Parameters (see Appendix B). The Barrey Ratio box was checked by default on all non-U.S. cases, but not on U.S. cases. The parameter has been potentially miscalculated since 06-Aug-2019.
- Medtronic detected this anomaly internally. Medtronic has not received any customer complaints associated with the Barrey Ratio issue.

Lenke Classification

- **Lenke Classification** defines the type of curve, the lumbar modifier and the sagittal modifier in order to categorize classification of adolescent idiopathic scoliosis (AIS).⁴ The classification system has three components:
 - Curve type (1 through 6)
 - A lumbar spine modifier (A, B, or C)
 - A sagittal thoracic modifier (-, N, or +).
- The curve types describe structural and nonstructural curves in the proximal thoracic, main thoracic, and thoracolumbar/lumbar regions. The lumbar spine modifier is based on the relationship of the center sacral vertical line (CSVL) to the apex of the lumbar curve. The sagittal thoracic modifier is based on the thoracic sagittal curve profile (T5-T12).
- The Lenke Classification calculated by the UNiD Spine Analyzer imports cobb angles that may not correspond to the angles required in the Lenke Classification criteria. As a result, the Lenke Classification is not adapted to the patient anatomy.

³ Barrey C, Jund J, Nosedà O, Roussouly P. Sagittal balance of the pelvis-spine complex and lumbar degenerative diseases. A comparative study about 85 cases. Eur Spine J. 2007 Sep;16(9):1459-67. doi: 10.1007/s00586-006-0294-6. Epub 2007 Jan 9. PMID: 17211522; PMCID: PMC2200735.

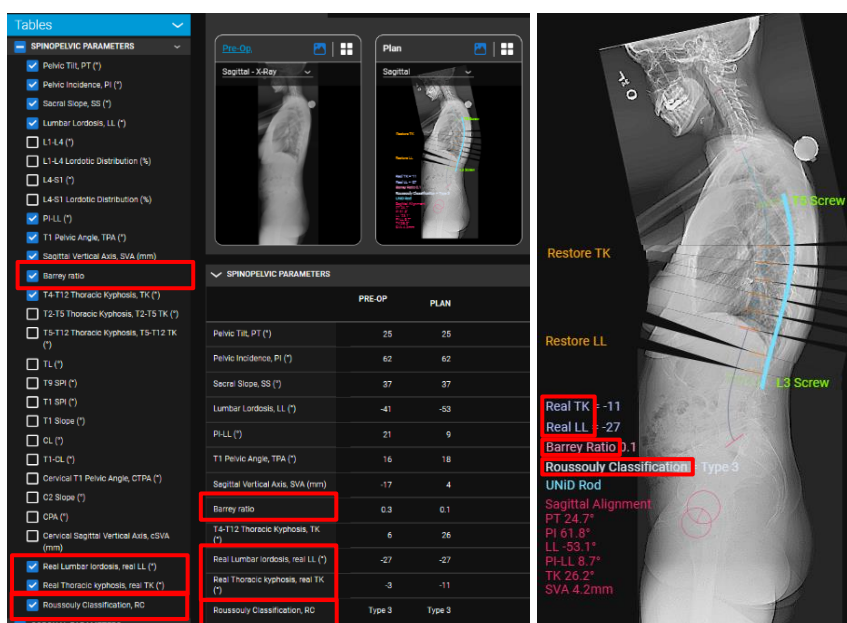
⁴ Lenke, Lawrence G. MD; Betz, Randal R. MD; Harms, Jürgen MD; Bridwell, Keith H. MD; Clements, David H. MD; Lowe, Thomas G. MD; Blanke, Kathy RN. Adolescent Idiopathic Scoliosis: A New Classification to Determine Extent of Spinal Arthrodesis. The Journal of Bone & Joint Surgery 83(8):p 1169-1181, August 2001.

- The Lenke Classification is an optional tool in the UNiD Spine Analyzer workflow and was only displayed in the UNiD HUB (Appendix B) or the O.R. Case Memo (Appendix C) if the Medtronic UNiD Lab Engineer calculated and applied Lenke Classification. The parameter has been potentially miscalculated since 09-Oct-2018.
- Medtronic has received seven (7) customer complaints associated with this Lenke Classification issue.

Appendix B - Barrey Ratio, Real LL/Real TK, Roussouly Classification in the UNiD HUB

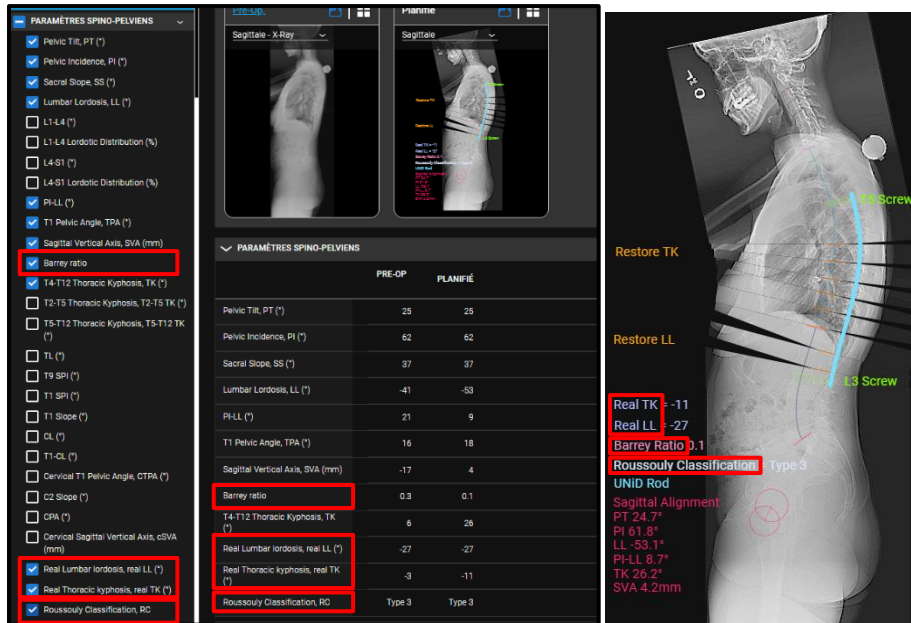
Barrey Ratio, Real LL/Real TK, Roussouly Classification, if selected, will appear under the list of Spinopelvic Parameters in the UNiD HUB parameter tables (left) and on the image itself (right). The parameters are highlighted in red boxes below.⁵

English



French

⁵ All images are included for illustrative purposes only and do not include any identifiable patient information.



Appendix C - Lenke Classification in the UNiD HUB and UNiD O.R. Case Memo Parameters

Lenke Classification, if calculated, will appear under the list of Coronal Parameters in the UNiD HUB (left) and on the Case Memo (right). Lenke Classification is highlighted in red boxes below. Roussouly Classification, Real LL/Real TK, and Barrey Ratio may also appear on the O.R. Case Memo.

English

Settings

Restore Defaults

Display Order

Tables

SPINOPELVIC PARAMETERS

CORONAL PARAMETERS

- ☒ Lenke Classification
- ☐ Proximal Thoracic Bend, PTB (°)
- ☐ Thoracic Bend, TB (°)
- ☐ Thoracolumbar Bend, TLB (°)
- ☒ Coronal Balance (mm)
- ☒ Cobb
- ☒ Level
- ☒ Angle (°)
- ☒ Apex
- ☒ Apex Distance to C7PL (mm)
- ☒ Apex Distance to CSVL (mm)
- ☒ Cobb
- ☒ Level
- ☒ Angle (°)
- ☒ Apex
- ☒ Apex Distance to C7PL (mm)
- ☒ Apex Distance to CSVL (mm)

IMAGES

Pre-Op. Sagittal - X-Ray

Plan Sagittal

SPINOPELVIC PARAMETERS

CORONAL PARAMETERS

	PRE-OP	PLAN
Lenke Classification	2C-	2C-
Coronal Balance (mm)	-10	-10
Cobb		
Level	T7-T11	T7-T11
Angle (°)	54	54
Apex		
Apex	T9	T9

UNiD O.R. Case Memo

01 PRE-OP FRONTAL 02 PRE-OP SAGITTAL 03 PLAN SAGITTAL 04 PLAN

STRATEGY

SPINOPELVIC PARAMETERS	PRE-OP	PLAN	CAGES	LEVELS
Pelvic Tilt (PT,°)	25	25		
Pelvic Incidence (PI,°)	62	62		
Sacral Slope (SS,°)	37	37		
Lumbar Lordosis (LL,°)	-41	-53		
PI-LL (°)	21	9		
Thoracic Kyphosis T4T12 (TK,°)	6	26		
Thoracic Kyphosis T2T12(TK,°)	-	-		
T1 Pelvic Angle (TPA,°)	16	18		
Sagittal Vertical Axis (SVA,mm)	-17	4		
Reverse Wedge (4°)				
FRONTAL PARAMETERS				
Cobb1	T7-T11	54		
Cobb2	T12-L4	-78		
Cobb3	L4-S1	10		
Lenke	2C-			

OSTEOTOMIES

LEVELS	LEVELS
Reverse Wedge (4°)	T11-T12
Reverse Wedge (4°)	T10-T11
Reverse Wedge (4°)	T9-T10
Reverse Wedge (4°)	TK
Reverse Wedge (4°)	T7-T8

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FA1444 Customer Acknowledgement Form - Response is required

UNiD Adaptive Spine Intelligence

Please complete this Form in its entirety.

Date: _____

Name of Person Completing this Form: _____

Title: _____

Direct Phone #: _____

Email: _____

Account Name: _____

Account Number: _____

Account Address: _____

City: _____ Zip Code: _____

Country: _____

I have read and understand the instructions provided and acknowledge receipt of the notification regarding the use of the UNiD Adaptive Spine Intelligence System by signing below. I also agree to further distribute and communicate this important information within my facility and to anyone whom I have further distributed the UNiD Adaptive Spine Intelligence System as required.

Name: (print) Signature: Date:

If you have any questions regarding this notification, please contact your Medtronic sales representative.

PLEASE EMAIL OR FAX THIS ACKNOWLEDGEMENT TO: rs.regulatoryuk-ire@medtronic.com