



## **Instructions for Completing the LASIK SURGERY OPERATIVE DATA REVIEW FORM**

This is a comprehensive set of instructions for completing the *LASIK Surgery Operative Data Review Form*. Refer to the explanation for each endnote as you enter the required information for each case you document.

- Document 50 consecutive cases of LASIK Surgery, including no more than 25 co-managed cases.
- Select cases where the original procedure was performed at least 6 months ago, to facilitate reporting of 6 months of follow-up data. (Follow-up information may be supplied by other eye care professionals.)
- Documented procedures must have been completed within the previous 18-month period, exclusive of procedures performed during a residency and/or fellowship.
- Do not include cases which were aborted due to reasons such as equipment malfunction, patient apprehension, anxiety, or concern, or anatomical/medical considerations (including prior corneal surgery).
- Document the number of cases that were excluded from your consecutive listing, and list the reasons for excluding these cases.
- Provide all the information requested for each case.
- Accurately identify each case to facilitate independent review of operative data.
- Sign and mail the completed *LASIK Surgery Operative Data Review Form*, along with your Application for Certification to the American Board of Eye Surgery.

Partial explanations of the data recorded for three sample cases follow. Study the examples carefully before you complete the form for each of your cases.

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Example 1

Rows 10, 11, 12: Manifest refract. 1<sup>st</sup> eye, Sph, Cyl, Axis; *NA* entered, no data from first eye available because this is the first eye for this patient

Row 23: Pre-existing ocular conditions; code *100* entered, none noted

Row 24: Pre-existing medical conditions; code *150* entered, none noted

Row 33: Type of microkeratome; code *1* entered, Chiron ACA used for keratectomy

Row 34: Mechanism of microkeratome; code *1* entered, automated

Row 36: Flap diameter (mm); *8* entered, 8 mm flap created

Row 40: Intraoperative complications/occurrences; code *200* entered, none noted

Row 48: Complications/unusual findings; code *300* entered, none noted

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Example 2

Rows 10, 11, 12: Manifest refract. 1<sup>st</sup> eye, Sph, Cyl, Axis; *NA* entered, no data from first eye available because this is the first eye for this patient

Row 23: Pre-existing ocular conditions; code *100* entered, none noted

Row 24: Pre-existing medical conditions; code *199* entered, asthma recorded

Row 29: Topographical findings; *NA* recorded, no unusual findings noted

Row 31: Procedure; code *2* entered, LASIK - spherical and laser astigmatism correction

Row 40: Intraoperative complications/occurrences; code *205* entered, fiber in interface

Row 53: Complications/unusual findings; code *305* entered, central island noted on topography

Row 54: Medical/surgical actions; code *401* entered, monitor and observe

Row 66: Intraoperative complications/occurrences; code *217* entered, mild irregular epithelial edge from flap lift

Row 73: Complications/unusual findings; code *305* entered, central island noted on topography

Row 74: Medical/surgical actions; code *400* entered, none required

Row 86: Intraoperative complications; code *200* entered, none noted

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Example 3

Rows 10, 11, 12: Manifest refract. 1<sup>st</sup> eye, Sph, Cyl, Axis; *NA* entered, no data from first eye available because this is the first eye for this patient

Row 14: Cycloplegic refract, operative eye, (in - cyl), Cyl Power; *NA* recorded, no cyl

Row 15: Cycloplegic refract, operative eye, Cyl Axis; *NA* recorded, no cyl axis

Row 23: Pre-existing ocular conditions; code *100* entered, none noted

Row 24: Pre-existing medical conditions; code *157* entered, hypertension noted

Row 31: Procedure; code *1* entered, LASIK - spherical correction only

Row 33: Type of microkeratome; code *2* entered, Hansatome specified

Row 35: Plate thickness; code *1* entered, 130 plate specified

Row 40: Intraoperative complications/occurrences; code *203* entered, corneal abrasion noted

Row 53: Complications/unusual findings; code *309* entered, epithelial ingrowth with surgical intervention indicated

Row 54: Medical/surgical actions; codes *407*, *409* and *416* entered, epithelium was removed, a soft contact lens was dispensed, and the patient was placed on NSAID

Row 66: Intraoperative complications/occurrences; code *200* entered, none noted

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	Row	Topic	1	2	3
Preoperative Data	1	Case number	001	002	003
	2	Eye (1=Right, 2=Left)	1	1	2
	3	Eye (1=First, 2=Second)	2	1	2
	4	Sex (1=Male, 2=Female)	1	1	2
	5	Age	27	33	48
	6	Stable refraction at least one year (0=no, 1=yes)	1	1	1
	7	Race/Ethnicity <sup>A</sup>	3	3	3
	8	VAsc	20/400	20/400	20/CF
	9	VAcc	20/20	20/25	20/20
	10	Manifest refract. 1st eye, Sph	NA	NA	NA
	11	Manifest refract. 1st eye, Cyl Power (in - cyl)	NA	NA	NA
	12	Manifest refract. 1st eye, Cyl Axis	NA	NA	NA
	13	Cycloplegic refract. operative eye, Sph	-5.50	-10.25	-7.75
	14	Cycloplegic refract. operative eye, (in - cyl), Cyl Power	-1.25	-1.00	NA
	15	Cycloplegic refract. operative eye, Cyl Axis	090	075	NA
	16	IOP (mm Hg)	14	13	16
	17	K (low)	43.39	42.51	44.72
	18	K (high)	45.81	43.72	45.11
	19	K (axis of high K)	110	166	017
	20	Pre-op pachymetry (microns)	580	510	600
	21	Predicted final refract. (In spherical equivalent)	p1	-0.75	-1.0
	22	Predicted final VAsc	20/20	20/40	20/40
	23	Pre-existing ocular conditions <sup>B</sup>	100	100	100
	24	Pre-existing medical conditions <sup>C</sup>	150	199 Asthma	157
	25	Pupil size (mm)	3	4	3
	26	Contact lens wear (0=no, 1=yes)	1	0	0
	27	If "yes" in 25, date of last wear	3/31/98	NA	NA
	28	Type of contact lens (1=hard, 2=soft)	2	NA	NA
	29	Topographical findings <sup>D</sup>	NA	NA	NA
Operative Data	30	Date of operation	4/28/98	10/2/97	5/12/98
	31	Procedure <sup>E</sup>	2	2	1
	32	Type of excimer laser <sup>F</sup>	2	2	2
	33	Type of microkeratome <sup>G</sup>	1	1	2
	34	Mechanism of microkeratome <sup>H</sup>	1	1	1
	35	Plate thickness <sup>I</sup>	1	2	1
	36	Flap diameter (mm)	8	8	9
	37	Targeted refract. (goal)/sph	Plano	-1.75	-1
	38	Targeted refract. (goal)/cyl (in - cyl)	0	0	NA
	39	Targeted refract. (goal)/axis	090	075	NA
	40	Intraoperative complications/occurrences <sup>J</sup>	200	205	203
	41	Epithelial abrasions (0=no, 1=yes)	0	0	1
	42	If "yes" in 41, size in mm	NA	NA	1
	43	Total ablation depth (microns)	64	98	82
	44	Residual corneal thickness (microns) <sup>K</sup>	386	252	388
	45	Abort procedure (0=no, 1=yes. Document Reason. )	0	0	0
First Postoperative Visit	46	Date of first postoperative visit	4/29/98	10/3/97	5/13/98
	47	VAsc	20/20	20/200	20/40
	48	Complications/unusual findings <sup>L</sup>	300	300	308
	49	Medical/surgical actions <sup>M</sup>	400	400	409

	Row	Topic	1	2	3
Complications/ Unusual Findings	50	Case number (same as Row 1)	001	002	003
	51	Date of new complications/unusual findings <sup>N</sup>	NA	10/28/97	6/1/98
	52	VAsc		20/200	20/60
	53	Complications/unusual findings <sup>L</sup>		305	309
	54	Medical/surgical actions <sup>M</sup>		401	407,409,416
First Enhancement	55	Date first enhancement performed <sup>O</sup>	NA	1/17/98	9/9/98
	56	Pre-enhancement VAsc		20/200	20/100
	57	Pre-enhancement VAcc		20/50	20/20
	58	Pre-enhancement refract., Sph		+2.00	-2.00
	59	Pre-enhancement refract. (in - cyl), Cyl Power		-3.25	-0.50
	60	Pre-enhancement refract., Cyl Axis		060	180
	61	Refraction technique (1=cycloplegic, 2=manifest)		2	2
	62	Pre-enhancement K (low)		41.76	41.72
	63	Pre-enhancement K (high)		43.81	42.84
	64	Pre-enhancement K (axis of high K)		100	012
	65	Pre-enhancement pachymetry (microns)		430	550
	66	Intraoperative complications/occurrences <sup>J</sup>		217	200
	67	Epithelial abrasions (0=no, 1=yes)		0	0
68	If "yes" in 67, size in mm		NA	NA	
69	Total ablation depth (microns)		18	25	
70	Residual corneal thickness (microns) <sup>K</sup>		252	365	
Complications/ Unusual Findings	71	Date of new complications/unusual findings <sup>N</sup>	NA	2/18/98	NA
	72	VAsc		20/200	
	73	Complications/unusual findings <sup>L</sup>		305	
	74	Medical/surgical actions <sup>M</sup>		400	
Second Enhancement	75	Date second enhancement performed <sup>O</sup>	NA	4/29/98	NA
	76	Pre-enhancement VAsc		20/200	
	77	Pre-enhancement VAcc		20/30+	
	78	Pre-enhancement refract., Sph		+1.50	
	79	Pre-enhancement refract. (in - cyl), Cyl Power		-1.50	
	80	Pre-enhancement refract., Cyl Axis		92	
	81	Refraction technique (1=cycloplegic, 2=manifest)		2	
	82	Pre-enhancement K (low)		39.11	
	83	Pre-enhancement K (high)		40.62	
	84	Pre-enhancement K (axis of high K)		002	
	85	Pre-enhancement pachymetry (microns)		416	
	86	Intraoperative complications/occurrences <sup>J</sup>		200	
	87	Epithelial abrasions (0=no, 1=yes)		0	
88	If "yes" in 87, size in mm		NA		
89	Total ablation depth (microns)		8		
90	Residual corneal thickness (microns) <sup>K</sup>		248		
Three-Month or Last Postoperative Visit	91	Date of last postoperative visit <sup>P</sup>	12/19/98	7/19/98	4/22/99
	92	VAsc	20/20	20/40	20/40
	93	VAcc	20/20	20/30+	20/20
	94	Loss of 2 or more lines of best corrected VA <sup>Q</sup>	NA	NA	NA
	95	Refract., Sph	-0.25	+0.50	-0.75
	96	Refract. (in - cyl), Cyl Power	-0.25	-0.75	-0.25
	97	Refract., Cyl Axis	072	116	038
	98	Refraction technique (1=cycloplegic, 2=manifest)	2	2	2
	99	IOP (mm Hg)	15	13	16
	100	Post-LASIK/Post-enhancement K (low) <sup>R</sup>	41.87	38.66	41.28
	101	Post-LASIK/Post-enhancement K (high) <sup>K</sup>	42.23	39.12	42.50
	102	Post-LASIK/Post-enhancement K (axis of high K) <sup>R</sup>	170	025	088
	103	Post-LASIK/Post-enhancement pachymetry (microns) <sup>R,S</sup>	525	400	520

## KEY TO ENDNOTES

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A. **Race/ethnicity:** *(Row 7; enter appropriate code .)*

- 1 Asian
  - 2 Black
  - 3 White
  - 4 Hispanic Origin
  - 9 Other *(Please specify .)*
- 

B. **Pre-existing ocular conditions:** *(Row 23; enter all codes that apply .)*

- 100 None
  - 101 Amblyopia
  - 102 Corneal opacity
  - 103 Dry eyes
  - 104 Keratitis sicca
  - 105 Keratoconus
  - 106 Myopic retinal degeneration
  - 107 Ocular hypertension
  - 108 Post cataract
  - 109 Post PKP
  - 110 Post radial keratotomy
  - 111 Post traumatic laceration
  - 112 Presbyopia
  - 113 Prior keratitis (e.g., herpes simplex or herpes zoster)
  - 114 Pupillary abnormality
  - 115 Refraction instability
  - 149 Other *(Please specify .)*
- 

C. **Pre-existing medical conditions:** *(Row 24; enter all codes that apply .)*

- 150 None
  - 151 AIDS
  - 152 Autoimmune disease
  - 153 Bleeding disorder
  - 154 Collagen vascular disease
  - 155 Diabetes
  - 156 HIV+
  - 157 Hypertension
  - 158 Pregnant/lactating
  - 199 Other *(Please specify .)*
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D. **Topographical findings:** *(Row 29; enter all codes that apply.)*

- 1 Keratoconus
  - 2 Irregularity of cornea
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E. **Procedure:** *(Row 31; enter appropriate code.)*

- 1 LASIK - spherical correction only
  - 2 LASIK - spherical and laser astigmatism correction
  - 3 LASIK - spherical and AK astigmatism correction
  - 4 LASIK - laser astigmatism
- 

F. **Type of excimer laser:** *(Row 32; enter appropriate code.)*

- 1 Visx 20/20
  - 2 Visx Star S2
  - 3 Summit Apex
  - 4 Summit Apex Plus
  - 5 Custom
  - 6 Technolas 217C-LASIK
  - 7 Nidek EC-5000
  - 9 Other *(Please specify.)*
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G. **Type of microkeratome:** *(Row 33; enter appropriate code.)*

- 1 Chiron Automated Corneal Shaper
  - 2 Chiron Hansatome
  - 3 Laser Sight ADK
  - 4 Moria LSK Carriazo-Barraquer
  - 5 Moria The One
  - 6 Solan Flapmaker
  - 9 Other *(Please specify.)*
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H. **Mechanism of microkeratome:** *(Row 34; enter appropriate code.)*

- 1 Automated
  - 2 Manual
  - 9 Other *(Please specify.)*
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I. **Plate thickness:** (Row 35; enter appropriate code.)

- 1 130
  - 2 160
  - 3 180
  - 9 Other (Please specify.)
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J. **Intraoperative complications/occurrences:** (Rows 40, 66, and 86; enter appropriate code. Be sure to annotate all intraoperative complications/occurrences, and the medical/surgical action[s] taken as per Endnote M.)

- 200 None
  - 201 Blade fragments
  - 202 Blood in interface
  - 203 Corneal abrasion (epithelial)
  - 204 Epithelial sloughing
  - 205 Fiber or filament in interface
  - 206 Flap—buttonhole
  - 207 Flap—decentration, clinically significant (i.e., less than 3 m of treatable bed on each side of pupil)
  - 208 Flap—incomplete & compromising laser ablation (i.e., less than 3 mm of treatable bed on each side of pupil)
  - 209 Flap—too thin
  - 210 Flap—too small (i.e., less than 3 mm of treatable bed on each side of pupil)
  - 211 Flap—transected in or near visual axis (i.e., less than 3 mm of treatable bed on each side of pupil)
  - 212 Free cap
  - 213 Globe penetration
  - 214 Irregular bed—mild
  - 215 Irregular bed—moderate
  - 216 Irregular bed—severe
  - 217 Irregular epithelial edge—mild
  - 218 Irregular epithelial edge—moderate
  - 219 Irregular epithelial edge—severe
  - 299 Other (Please specify.)
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K. **Residual corneal thickness:** (Rows 44, 70 and 90.)

Residual corneal thickness = Pre-op pachymetry – (Plate thickness + Total ablation depth)

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L. **Complications/unusual findings:** (Rows 48, 53, and 73; enter all codes that apply. Be sure to annotate all complications/unusual findings, and the medical/surgical action[s] taken as per Endnote M. )

- 300 None
  - 301 Ablation decentration compromising vision
  - 302 Blade fragments
  - 303 Blood in interface
  - 304 Case lost to follow-up
  - 305 Central islands
  - 306 Confluent haze
  - 307 Consecutive hyperopia
  - 308 Corneal abrasion
  - 309 Epithelial ingrowth with surgical intervention indicated
  - 310 Fiber filaments interfering with vision or causing a reaction
  - 311 Flap dislocation with surgical intervention indicated
  - 312 Folds in flap with surgical intervention indicated
  - 313 Interface debris with surgical intervention indicated
  - 314 Interface infection
  - 315 Interface inflammation syndrome
  - 316 Intrastromal haze
  - 317 Irregular astigmatism
  - 318 Irregular astigmatism with surgical intervention indicated
  - 319 Punctate epithelial keratopathy
  - 320 Residual myopia
  - 321 Small optical zone
  - 322 Sterile infiltrates in flap
  - 323 Sterile infiltrates in interface
  - 399 Other (*Please specify .*)
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M. **Medical/surgical actions:** (Rows 49, 54, and 74; enter code(s) corresponding to medical/surgical actions required **to treat for intraoperative complications/ occurrences** [Endnote J], **or for complications/unusual findings** [Endnote L], excluding subsequent surgical enhancements. Enter all codes that apply. Do not record routine actions.)

- 400 None
- 401 Monitor/observe
- 402 Ablate central island after lifting flap
- 403 Amputate flap
- 404 Dispense antibiotic—subconjunctival
- 405 Dispense antibiotic—systemic
- 406 Dispense antibiotic—topical
- 407 Dispense nonsteroidal anti-inflammatory drug (NSAID) drops
- 408 Dispense ocular lubricants
- 409 Dispense soft contact lens
- 410 Dispense steroid drops
- 411 Enhancement
- 412 Keratoplasty—penetrating or lamellar
- 413 Lift, irrigate, smooth, and replace flap
- 414 Perform patching
- 415 Punctal plugs
- 416 Remove epithelium from interface
- 417 Remove foreign and/or endogenous matter from interface
- 418 Suture flap
- 499 Other (Please specify.)

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N. **Date of new complications/unusual findings:** (Rows 51 and 71; record date for any visit[s] required for newly presenting complication[s]/unusual finding[s] requiring treatment during the 6-month postoperative period. If no incident[s] requiring treatment occurred, record NA on Row 51 and/or Row 71, and skip to Row 55 and/or Row 75. If necessary, complete Rows 52 through 54, and/or Rows 72 through 74, to record data for incident[s] requiring treatment during the 6-month postoperative period. Use additional space to document any and all subsequent incidents that occurred during the 6-month postoperative period.)

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O. **Date first and second enhancements performed:** (Rows 55 and 75; record date for the first and/or second visit[s] during which an enhancement procedure was performed during the 6-month postoperative period. If no incident[s] requiring treatment occurred, record NA on Row 55 and/or Row 75, and skip to Row 91 .)

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P. **Date of last postoperative visit:** (Row 91; indicate the date of the last visit during the 12-month postoperative period. Information may be supplied by another eye care professional, but must be based on postoperative examination at least 3 months after the initial operative procedure. Record NA if the case was lost to follow-up .)

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Q. **Loss of 2 or more lines of best corrected VA:** (Row 94; if patient experienced a loss of 2 or more lines of best corrected vision, please enter code[s] for all pre-existing conditions [Endnotes B and/or C] and/or complications or unusual findings [Endnote L] which account for the visual result .)

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R. **Post-LASIK/Post-enhancement K:** (Rows 100, 101, 102, and 103; for cases not requiring enhancements, record Post-LASIK, non-enhancement status. For cases requiring enhancements, record post-enhancement status.)

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S. **Post-LASIK/Post-enhancement pachymetry:** (Row 103; record if available.)

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