

appears that area of square 8 receives the total 4 pulses at each axis; area 7 receives 3 (4 - 1) pulses; area 6 receives 2 (4 - 2) pulses; and area 5 receives 1 (4 - 3) pulse. However, in Figure 2.2-1, you marked that areas (8 - 5) along the axis  $0^\circ$  receive all of 4 pulses at axis of  $0^\circ$  and areas (8 - 5) along the axis  $90^\circ$  receive all of 4 pulses at axis of  $90^\circ$ . Please explain this discrepancy.

31. With respect to the profiles of your ablated PMMA samples:

- a. The PMMA ablations for the spherical myopia (Fig 1-3), appear to have a "hump" in the bottom. Please explain the causes and discuss the potential impact of this "hump" on safety and effectiveness. In addition, your PMMA ablation curves did not include theoretical curves. Please provide plots of PMMA ablations versus the theoretical curves.
- b. The PMMA ablations for the astigmatism (Fig 7-15) appear to be notably asymmetric. In particular, the asymmetry seems to be about 25% of the ablation depth in the maximal astigmatism as shown in Fig 9. Also, since you stated that (in Table 3-2) the signal to noise ratio was too low to obtain meaningful data at  $-0.5$  D cylinder, you should improve the quality of the laser beam to enhance the signal to noise ratio. This might improve the quality of your astigmatic ablations. After improving the quality of your laser beam, please provide PMMA ablations for the astigmatism profiles to include sections through both axes, and plot these ablations versus the theoretical curves.

32. With respect to the software, please provide the following information:

- a. Software Description: description and flowchart of the software lifecycle of the device, a flow diagram and narrative about the function of the software and about how the software interacts with the hardware.
- b. Software Requirements Specifications (SRS): the Software Requirements Specification document, which clearly documented their functional, performance, interface, design and development requirements.
- c. Validation (including verification and testing): an acceptable description of the systematic process of life cycle activities, including analysis, evaluation, assurance and testing of the software, and supporting documentation. This included a description of the activities and protocols at the unit, integration and system level, including pass/fail criteria, test reports, summaries and tests results.
- d. Certification: if the software design, development and maintenance system have been certified to an international or national standard, specify to which standard and provide the name of the organization that performed the certification.