



Document History / Approval Form

Document Number:		Relates to Catalog #:
Document Title: PRIMA Scanning Station Software Requirements Document		
Revision	Description of Change	Effective Date
A	Release per ECR #00-01	

Reviewer's Title	Reviewer's Sign Below	Date (dd/mm/yy)
Project Leader		/ /
Director of Product Development QA		/ /
Director of Software Engineering		/ /
Document Author	Helen Hill	/ /

PR1MA® Scanning Station
Software Requirements Document

Table of Contents

1. PURPOSE	7
2. DEFINITIONS.....	7
3. REFERENCES	7
4. SCANNING STATION DESCRIPTION.....	8
4.1 Product Concept	8
4.2 Function and Operational Impact.....	11
4.3 Interfaces and Operating Environment	11
4.3.1 Operating Environment.....	13
4.4 User Characteristics	13
4.5 General Design Constraints	14
4.5.1 Hardware Limitations	14
4.5.2 Parallel Operation	14
4.5.3 Safety Considerations	14
4.5.4 Security Considerations	15
4.5.5 Error Handling.....	15
4.6 Assumptions and Dependencies.....	15
4.7 Software Performance.....	16
5. DETAILED SOFTWARE REQUIREMENTS	17
5.1 Application Software Requirements	17
5.2 Application Software Components	18
5.3 Graphical User Interface.....	19
5.4 Slide Delivery	21
5.4.1 Load Slides	21
5.4.2 Unload Slides.....	21
5.4.3 Control Vacuums Function	22
5.4.4 Park Robot Function	22
5.4.5 Release Robot Function	22
5.4.6 Initialize Robot Function	22
5.4.7 Program Robot Function.....	23
5.4.8 Barcode Reader Control Functions	23
5.5 Slide Mapping.....	26
5.5.1 SIF Data Format	26
5.6 Image Acquisition.....	28
5.6.1 Assumptions.....	28
5.6.2 Initialize	30
5.6.3 Capture	30
5.6.4 Hardware Specifications	36
5.6.5 Embedded Tests.....	38

5.7	Slide Analysis	41
5.7.1	Required Prerequisites	41
5.7.2	Specific Requirements	41
5.7.3	Low Resolution Scanning	42
5.7.4	Medium Resolution Scanning	44
5.7.5	Rescanning.....	45
5.7.6	Auxiliary Tasks Performed By Application Software.....	47
5.8	Reporting	52
5.8.1	Output Data Format	53
5.9	Alignment	56
5.9.1	Invocation	56
5.9.2	Low Resolution Focusing Function	56
5.9.3	Medium Resolution Focusing Function	57
5.9.4	High Resolution Focusing Function.....	57
5.9.5	Show White Balance Function.....	57
5.9.6	Stage Control Function	58
5.9.7	Objective Control Function	59
5.9.8	Robot Control Function	62
5.9.9	IP Control Function	63
5.9.10	SNAP Control Function.....	64
5.9.11	System Test Functions	65
5.9.12	Get Versions	68
5.9.13	CHK Vibration	68
5.10	Critical Algorithms	70
5.10.1	Unexpected Power Interruption Algorithm.....	70
5.10.2	Initialization Algorithm	71
5.10.3	Focusing Algorithm	71
5.10.4	Low Resolution Scan Algorithm.....	73
5.10.5	Medium Resolution Scan Algorithm.....	74
5.10.6	ReScan Algorithm.....	75
5.10.7	Read Barcode Labels Algorithm.....	76
5.10.8	QC Algorithm	77
5.11	Primary Classifier	79
5.12	Neural Networks.....	80
5.12.1	Neural Network Processor (NNP)	80
5.12.2	Specific Requirements	80
5.12.3	Design Constraints.....	81
5.12.4	Assumptions and Dependencies.....	81
5.12.5	Performance.....	82
5.12.6	Neural Network Training.....	82
5.12.7	Implementation in Slide Analysis	84

Table of Figures

Figure 1 PR1MA System Components	8
Figure 2 Scanning Station Architecture	10
Figure 3. Scanner Hardware Environment	12
Figure 4 GUI Screen Layout	20
Figure 5 Digitized Images	29
Figure 6. Focusing Algorithm	73
Figure 7. Read Barcode Labels	77
Figure 8 Interaction of the Primary Classifier and Neural Network Module	86
Figure 9 Neural Network Module for Squamous Cells	87
Figure 10 Neural Network Module for Cluster Cells	88

Table of Tables

Table 1 Scanner Users13
Table 2 SIF File Run Data Structure26
Table 3 SIF File Slide Data Structure27
Table 4 Image Acquisition Software Inputs29
Table 5 Image Acquisition Software Outputs30
Table 6 Low-Res Capture Inputs32
Table 7 Low-Res Capture Outputs32
Table 8 Output Images Specification.....32
Table 9 Med-Res Capture Inputs33
Table 10 Med-Res Capture Outputs34
Table 11 Output Images Specification.....34
Table 12 Output Scanmap Specification34
Table 13 High-Res Capture Inputs35
Table 14 High-Res Capture Outputs.....35
Table 15 Output images specification35
Table 16 Stage Properties36
Table 17 Slide Holder Properties37
Table 18 Slide Holder Performance38
Table 19 Optical Performance38
Table 20 Image Acquisition Testing.....39
Table 21 QC TECH Codes49
Table 22 CMP File First Header54
Table 23 CMP File Second Header54
Table 24 CMP File First Slide Image Header.....55
Table 25 CMP File Second Slide Image Header55

1. PURPOSE

The purpose of this document is to provide a description of the requirements pertinent to the development of the analytic software that comprises the PR1MA Scanning Station. These requirements are intended for use by seasoned software engineers whose tasks shall be to design, implement, test, and maintain the software products described in this document.

2. DEFINITIONS

Following are the terms specific to this document:

- System: PR1MA ® System
- Subsystems: The Subsystems defined for the PR1MA® System will be:
 - PR1MA Scanning Station
 - PR1MA Server Computer
 - PR1MA Review Station
 - PR1MA Workstation
- Application Software : The proprietary software resident in the PR1MA Scanning Station. The topic of this document.

3. REFERENCES

The following references are related to the software products discussed in this document and should be consulted as necessary.

Document Number	Document Name
701A001	PAPNET Testing System 2.00 SDS
701B0011	PAPNET Testing System 2.00 SR, Project #0085
701B0012	Slide Requirements
TICI Document No. 255-SCN-010-001	Alignment CSCI of the Scanner Development Project

4. SCANNING STATION DESCRIPTION

4.1 Product Concept

The Scanning Station shall be one of four Subsystems (Scanning Station, Server Computer, Workstation, and Review Station) comprising the **PRIMA System** intended to analyze (scan) Pap smear slides for abnormalities. See Figure 1.

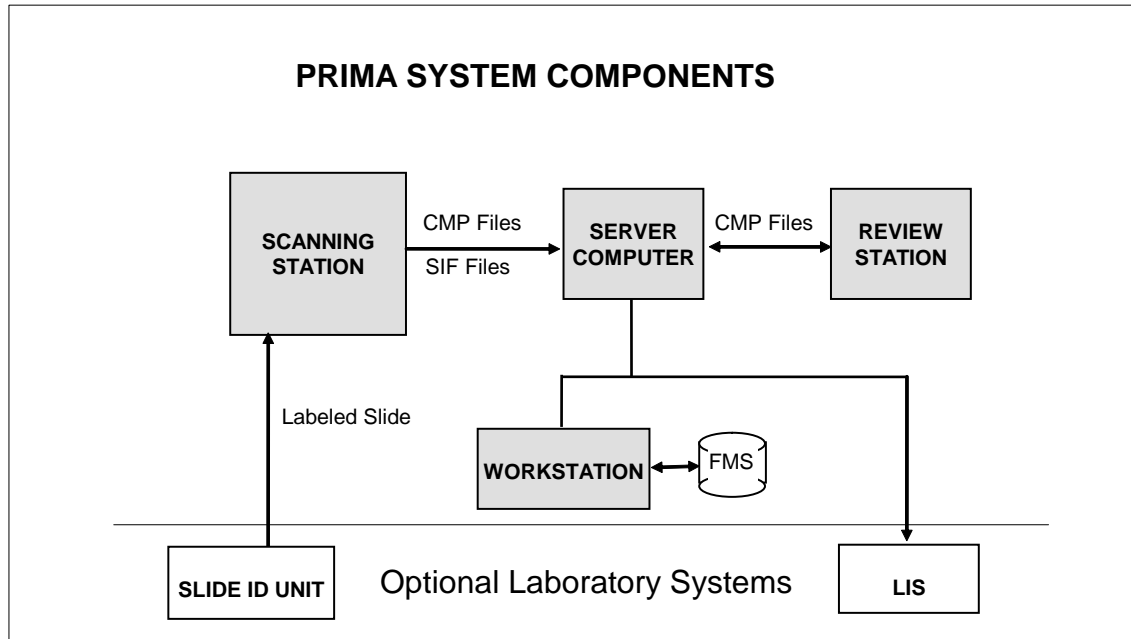


Figure 1 PR1MA System Components

The PR1MA system shall be designed to automatically screen conventionally prepared cervical Papanicolaou (PAP) smear slides for cell abnormalities, identify and mark the aberrant objects, and snap the images to be reviewed by cytotechnologists.

The PR1MA System is composed of:

- **Scanning Station.** Shall contain all the hardware and software necessary to map, analyze and report results for conventionally prepared cervical PAP smears.
- **Server Computer.** Shall be the primary storage device for saving compressed images (CMP Files) of the scanned files.
- **Review Station.** Shall display high resolution images of the suspect cells for review by the cytotechnologists.
- **NT Workstation Station.** Shall contain the File Management System (FMS) to track and update slide status.

The PR1MA System may interact with two additional laboratory systems:

- **Slide ID Unit.** An optional device used to print the barcode labels to be affixed to the slides.
- **Laboratory Information System.** An optional storage device and laboratory management system provided by the pathology laboratory.

The Scanner application software shall scan the slides using the Slide Delivery, Slide Mapping, Image Acquisition and Image Processing Hardware systems.

These systems shall provide the following functions (see Figure 2):

- **Slide Delivery Hardware.** Shall control the transfer of slides between the Slide Elevator, Slide Trays and Slide Holder and shall control the Barcode Reader.
- **Slide Mapping Hardware.** Shall examine each slide, mapping the area inside the cover slip and produce Slide Information Files (.SIF).
- **Image Acquisition Hardware.** Shall provide accurate positioning and fixing of the slide on the stage so that any part of the slide could be within the microscope field-of-view. Shall be used to view the cellular areas on the slide at low, medium and high resolution. Shall produce high resolution color images of the slide area centered below the optics.
- **Image Processing Hardware.** Shall contain high speed processors to run the primary cell selection and cell classification algorithms.

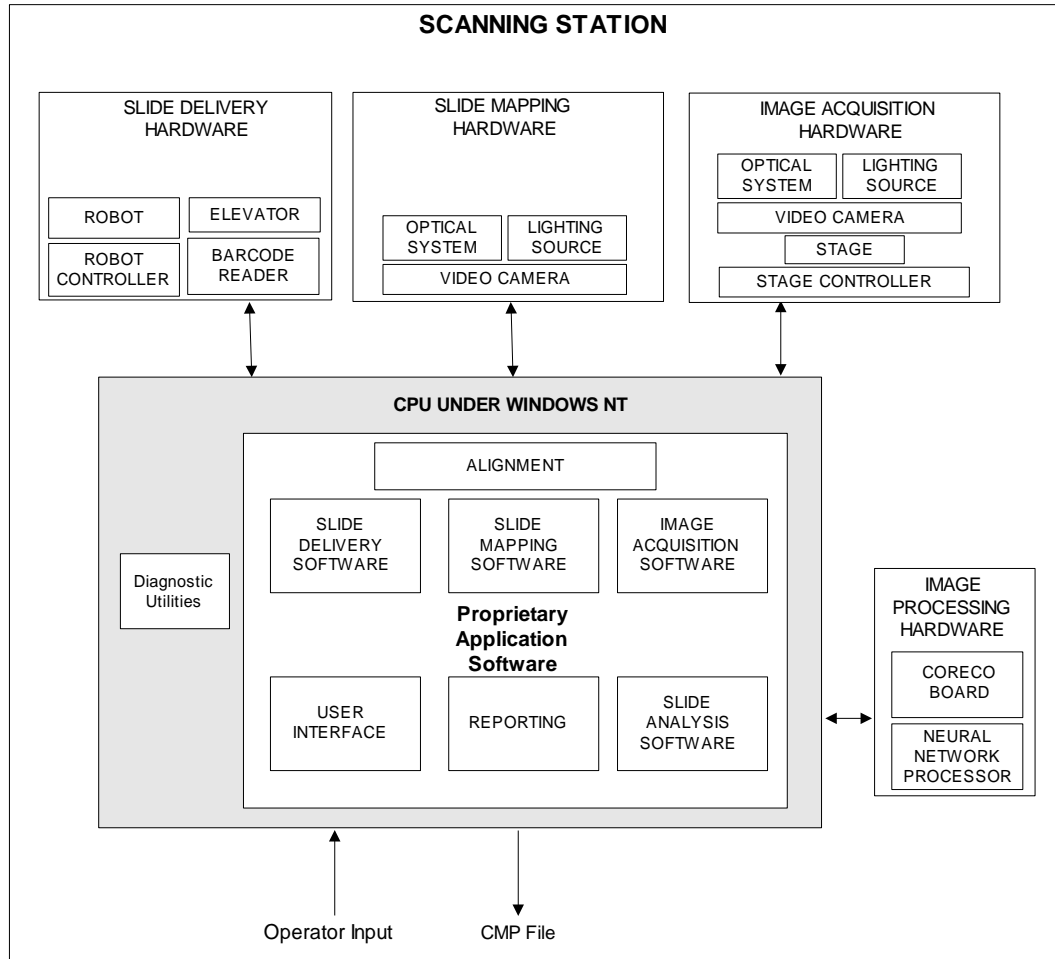


Figure 2 Scanning Station Architecture

4.2 Function and Operational Impact

The context relationships between the Scanner, Server Computer, Review Station, and Workstation are illustrated in Figure 1.

Slides presented to the Scanner must be labeled with properly formatted barcodes. The **Slide ID Unit** represents any device capable of printing the barcode labels to be affixed to the slides. The labeled slides shall be input to the Scanner. The **Scanner** shall scan the properly barcoded slides to produce high resolution compressed images (*.CMP Files*). The resulting high resolution compressed images shall be stored on the **Server Computer**. The high resolution compressed images shall be reviewed by the cytotechnologists on the **Review Station**. An NT **Workstation** shall contain a file management system to keep track of the compressed images.

4.3 Interfaces and Operating Environment

To allow running the proprietary and commercial software efficiently and to provide support to Windows NT and multiple interfaces, the communications between the Scanner's software and hardware shall be controlled by a Pentium based CPU over the ISA Bus. The components of the Slide Transfer, Slide Mapping and Image Processing Systems are illustrated in Figure 3. Detailed descriptions of the hardware components can be found in Document Number 701A0001, *PAPNET® Testing System - System Design Specification*.