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Director of Product Development QA		/ /
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PR1MA® Scanning Station

Software Requirements Document

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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 **PR1MA System** intended to analyze (scan) Pap smear slides for abnormalities. See Figure 1.

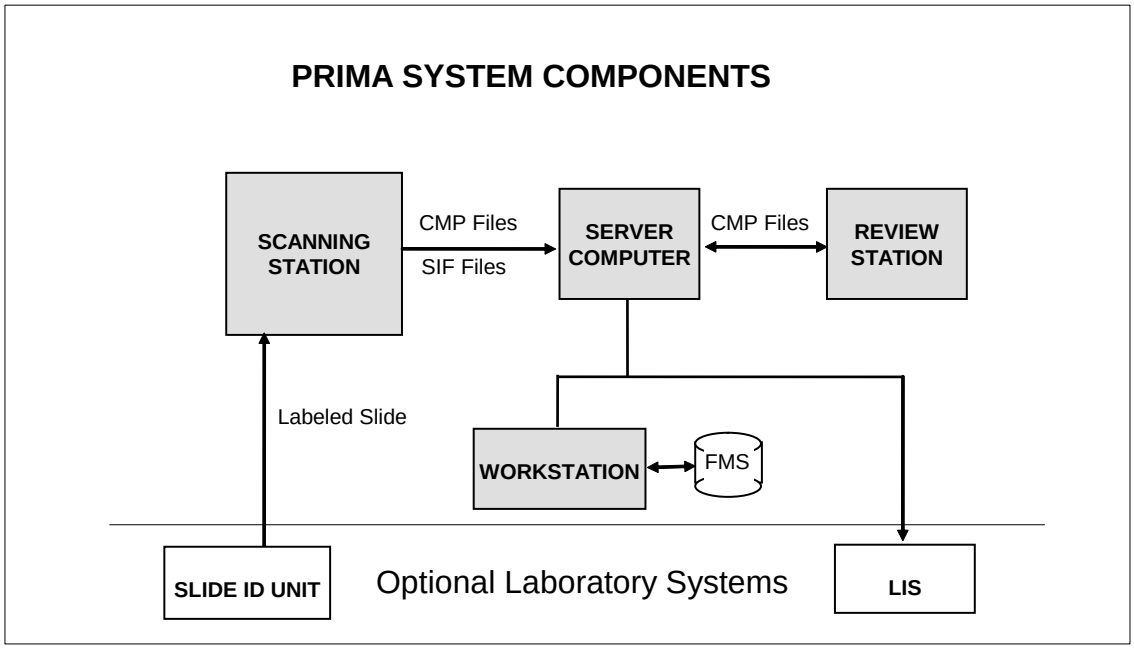

Figure 1 PR1MA System Components

The PR1MA system shall be designed to automatically screen conventionally prepared cervical Papanicolauo (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.

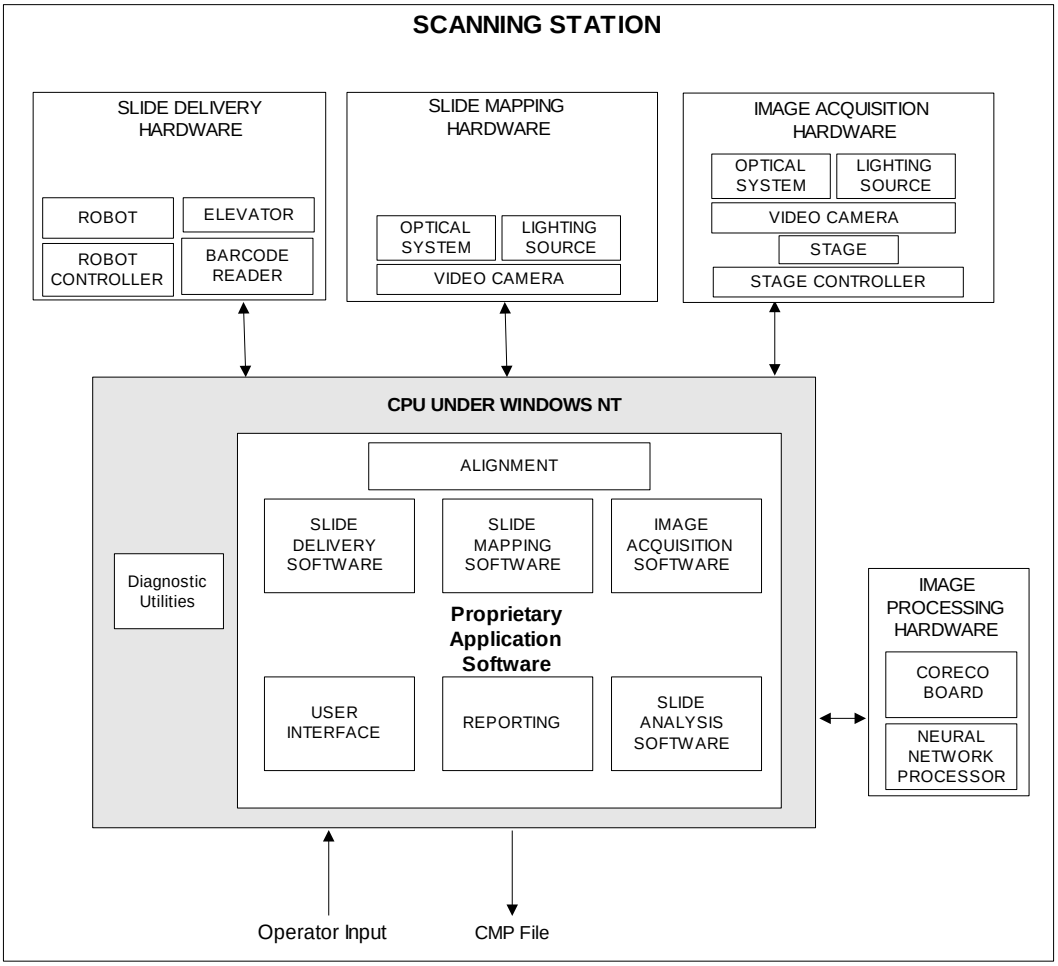

Figure 2 Scanning Station Architecture

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.