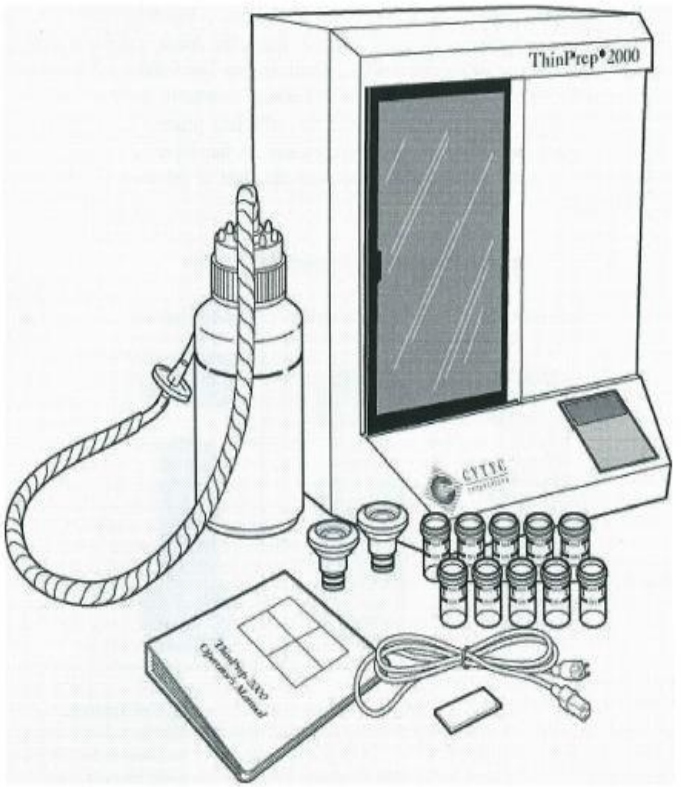
ThinPrep® 2000 System

RANKIN
BUILD A BETTER LAB



Last revision 2012

Transfer of the sample from the vial to the slide

1. The ThinPrep Pap Test Filter rotates within the sample vial, separating debris and dispersing mucus without adversely affecting the appearance of cells.

2. A gentle vacuum collects cells on the exterior surface of the Filter membrane. The ThinPrep 2000 monitors the rate of flow through the Filter.

3. After the cells are collected, the Filter is inverted and gently pressed against the ThinPrep Microscope Slide. Surface tension and air pressure cause the cells to adhere to the Slide, resulting in an even distribution within a circular area.

Materials Provided

- ThinPrep Processor Instrument Model 2000
- PreservCyt Solution Vial
- Gyn TransCyt Filter (clear)
- Program Memory Card
- Power Cord
- Filter Cap
- 2 spare filter seal O-rings
- High Vacuum Grease
- Waste Bottle Assembly
- ThinPrep Microscope Slides

Principles of Operation

- Sample Preparation/Instrument Loading
  - Before the ThinPrep Processor can process gynecological samples, the samples must be placed into PreservCyt Solution. (See Chapter 8)
  - In preparation for sample processing, the operator loads four essential items into the ThinPrep 2000 Processor:
    1. PreservCyt Vial
    2. TransCyt Filter attached to the filter cap
    3. ThinPrep Slide
    4. Fixative bath containing a standard laboratory fixative

- Start of Cycle
  - When the operator initiates a sequence, the ThinPrep 2000 Processor verifies installation of disposables, motor positions, and the positive and negative pressures on the pressure reservoirs. After this process the instrument processes the slide using the following sequence.

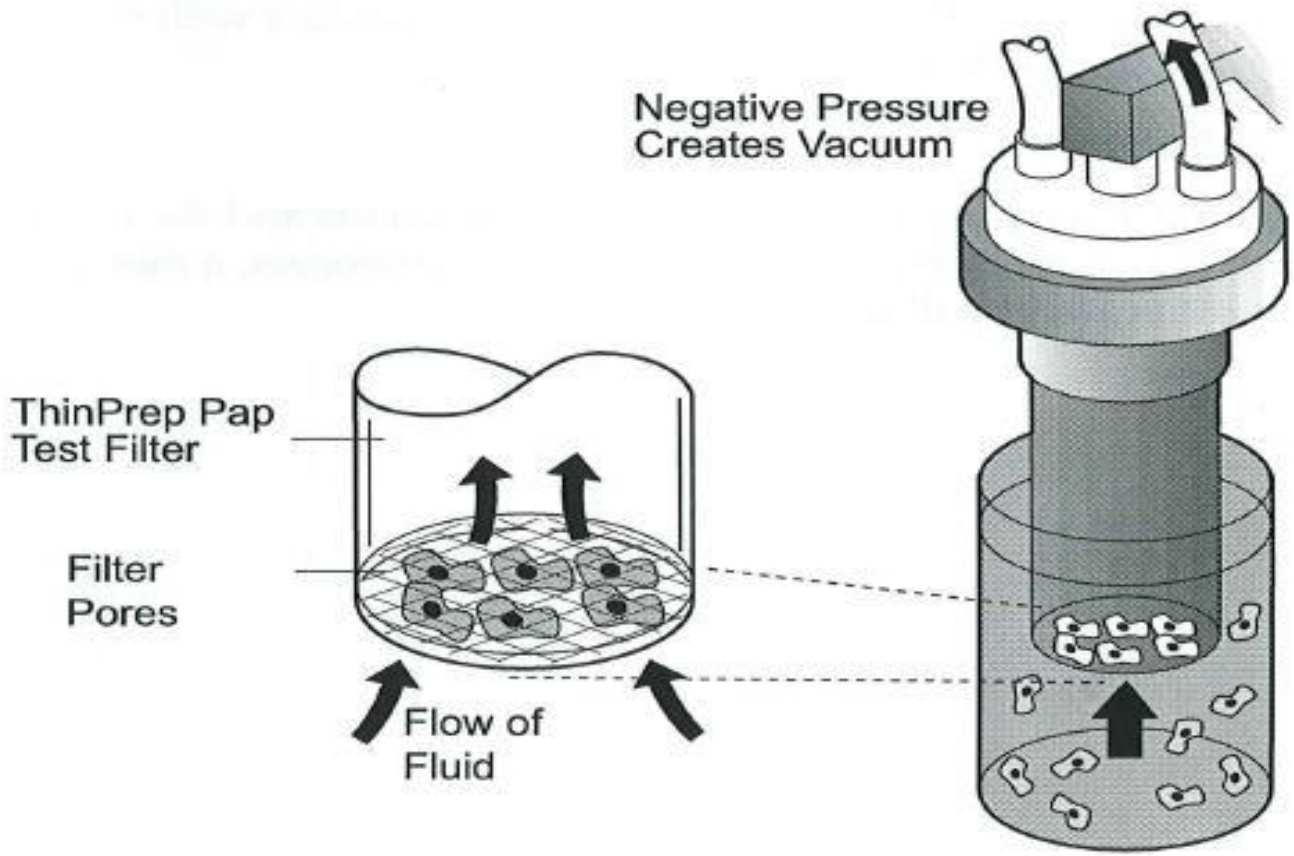
- Fluid Level Detection
  - The cap seal lowers to seal the filter assembly and the sample vial is raised towards the membrane. The sample vial stops when the filter membrane makes contact with the surface of the fluid. If the fluid level is satisfactory, the instrument will continue the slide preparation process.
    - An error message and audible alarm indicate an unsatisfactory fluid level

- Dispersion
  - The cap seal lifts and the dispersion system rotates the TransCyt Filter assembly within the cell suspension, creating shear forces that are strong enough to separate randomly joined material and disperse mucus, and are not known to have an adverse effect on the cellular architecture or on adhesive forces joining diagnostically relevant groups of cells.
- Filter Wetting
  - The head lowers to seal the filter assembly. Negative pressure is briefly applied, drawing a small amount of fluid through the TransCyt Filter to wet it. Following wetting, the system gently blows out the liquid in the TransCyt Filter. This clears an cellular material from the filter surface.

Cell Collection

- The filtering membrane is biologically neutral and is mounted at one end of the TransCyt Filter cylinder. The membrane is a flat, smooth, porous surface that collects the cellular material on one plane.
- The pneumatic system applies negative pressure to the filter in a series of pulses. These pulses draw PreservCyt solution through the filter membrane and collect suspended material onto the outer membrane surface.
- The process ceases when a target filter coverage, predetermined by the processor sequence, is attained.
- After collection, the cells sit on a single plane over the pores, ready for transfer to the slide.

Cell Collection

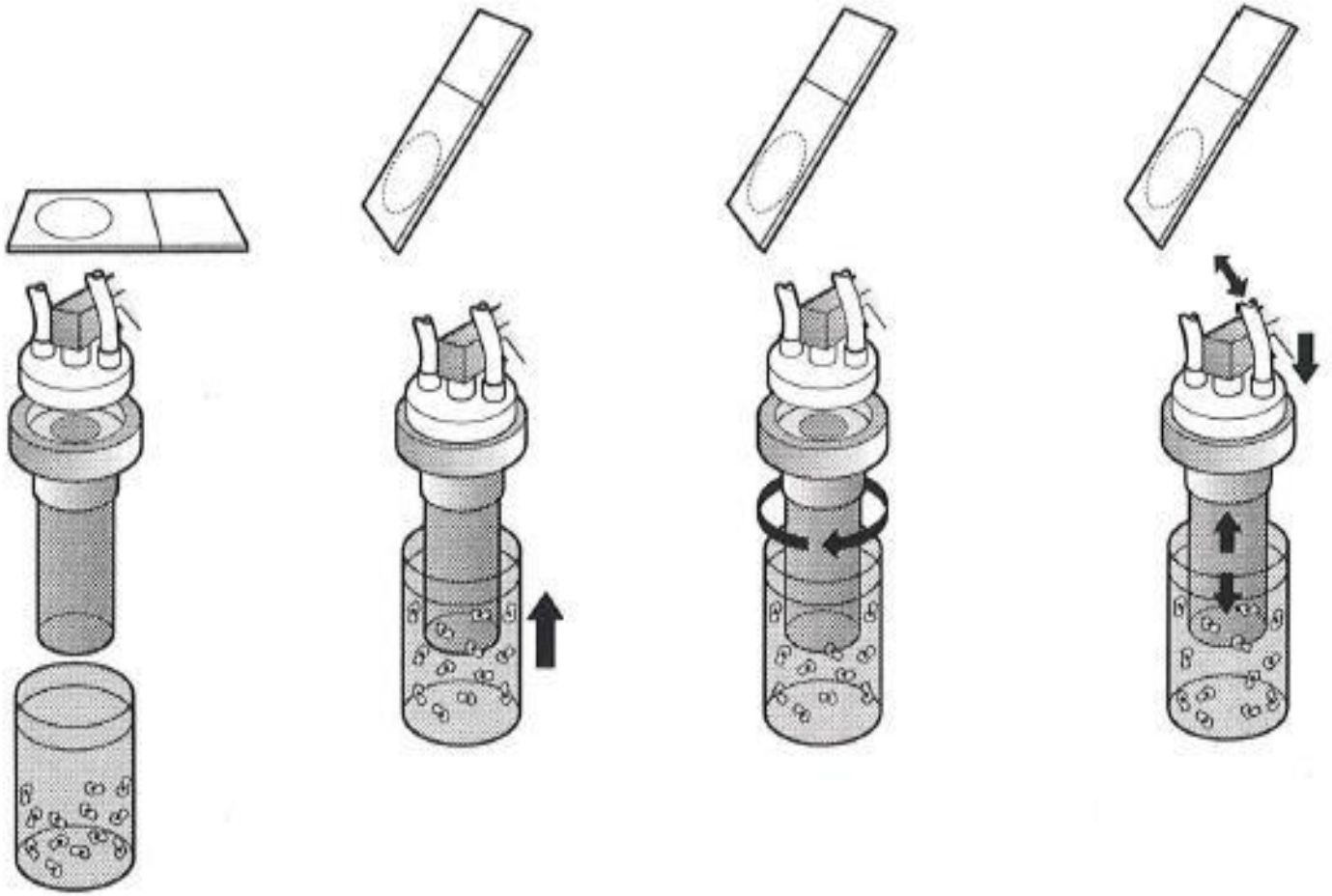


- Waste Clearing
  - When collection ends, the TransCyt Filter is withdrawn from the sample vial and the filtrate is aspirated into the waste bottle as the filter is inverted. The collected cells remain on the TransCyt Filter due to the negative holding pressure.
- Bubble Point
  - Removes excess fluid from the filter membrane prior to transferring cells onto the slide to enhance cell adhesion to the slide.
    - Performed after all of the fluid is evacuated.

- Cell Transfer
  - When bubble point is complete, the slide handler moves the slide into contact with the inverted TransCyt Filter.
    - The natural adhesion properties of cells and the electromagnetic charge of the glass slide are responsible for the transfer of cells from the membrane to the slide.
- Slide Ejection
  - Once cell transfer is complete, the slide is removed from contact with the filter and automatically ejected into the fixative bath vial.

- Cycle Completion
  - All the motorized mechanisms return to their initial positions and the display returns to the Main Menu.
    - If the system detects an error during the process, a message display and an audible alarm will sound.

Overview of Processing



1. Slide and TransCyt Filter are in place. Operator initiates sequence.

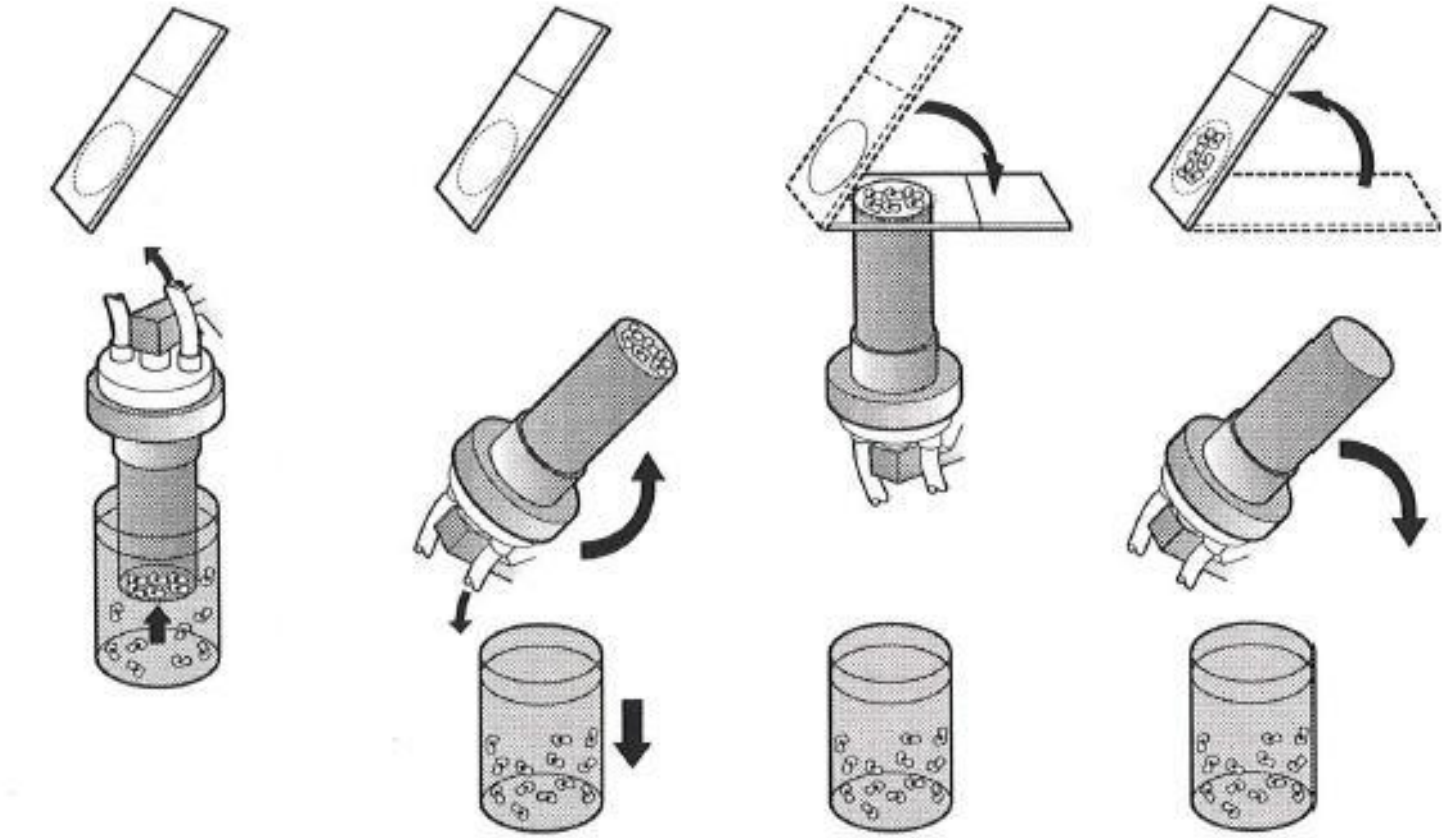
2. Elevator raises sample to filter and system checks for appropriate fluid level.

3. Dispersion. TransCyt Filter rotates to disperse sample material.

4. Filter Wetting. Liquid is drawn into the Filter then pushed out.

RANKIN
BUILD A BETTER LAB

Overview of Process



5. Collection. Sample is drawn onto TransCyt Filter in a controlled manner.

6. Waste Clearing. Filter is inverted, waste is cleared to waste bottle and sample vial is lowered.

7. Cell Transfer. Slide holder contacts filter. Cells are transferred to slide.

8. Slide Ejection. Slide is deposited into fixative bath. Filter returns to starting point.

Installation and Specifications

- Waste Bottle connection
- Inserting Program Memory Card
- Power Cord

- Powering up
  - With the door closed, turn on the power switch
  - As power is applied to the instrument, the control panel will display the following sequence messages

This message will appear for approximately four seconds:

```
        CYTYC ThinPrep®
Version V#.##
Computed CRC:  ####
Firmware CRC:  ####
```

At this point the system initializes all mechanisms while displaying this message for approximately four seconds:

```
        CYTYC ThinPrep®

Initializing System
Press STOP to Cancel
```

After initialization, the system calibrates all pressure sensors while displaying this message for approximately twenty seconds:

```
Presure Sensor
calibration in
progress.
Please wait.
```

If the system initialization and calibration were successful, the control panel display will read:

```
Main Menu: Select
1-SUPER                 4-GYN
2-FLU/FNA
3-MUCOID                ↓- MORE
```

The above message indicates that the system is in idle mode.

- Leave the power to the ThinPrep processor on all the time.
- Unit calibration occurs several time while the power is on:
  - At power up
  - 15 minutes after power up
  - 2 hours after power up
  - Every 8 hours thereafter

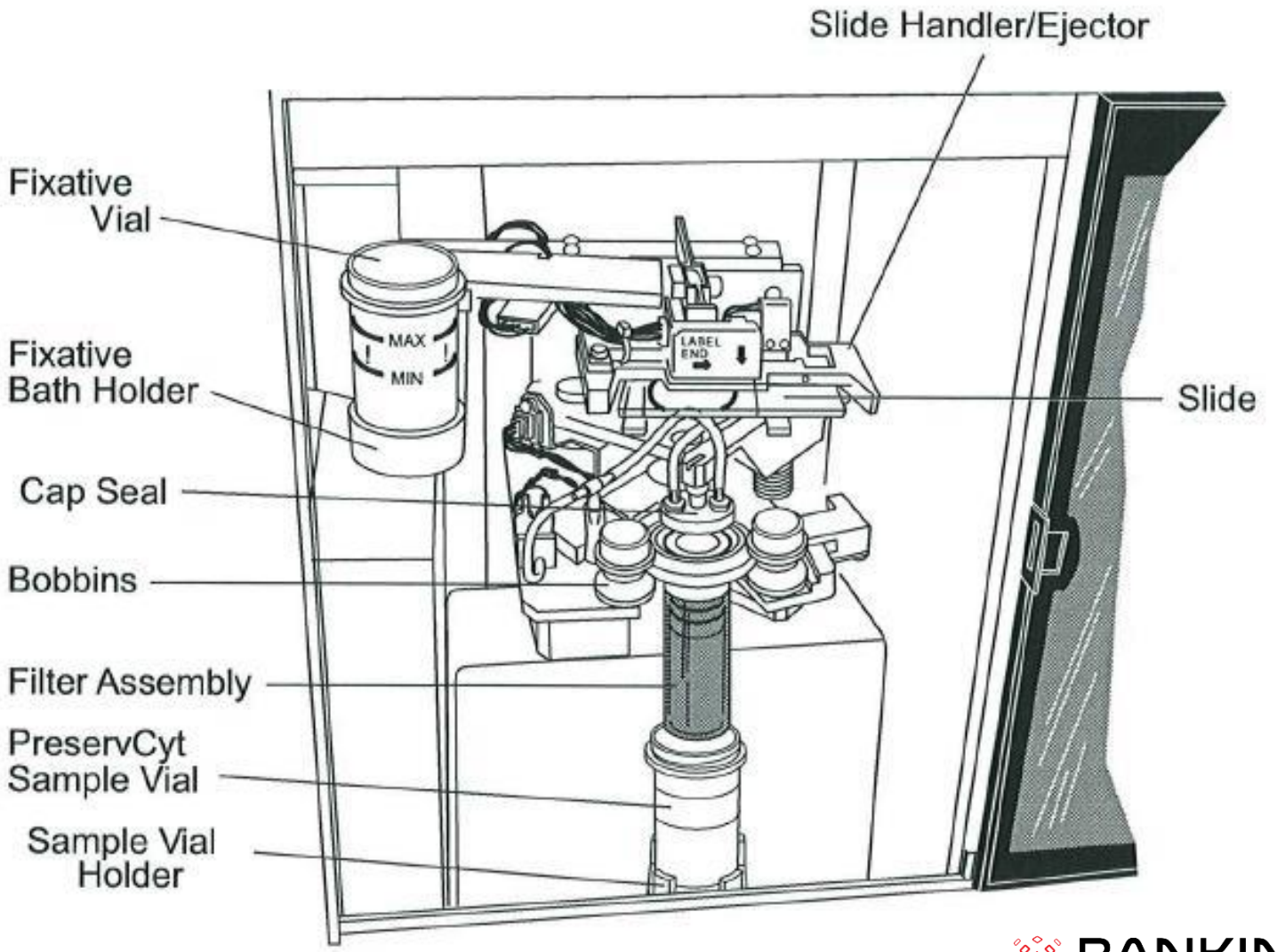
Operating Instructions

- Material Requirements:
  - PreservCyt Solution vial
  - TransCyt Filter
  - Filter Cap
  - Fixative Bath Vial
  - ThinPrep Slides
  - Gloves
  - Lint-Free wipes
  - Alcohol Bath

Pre-Operation Check List

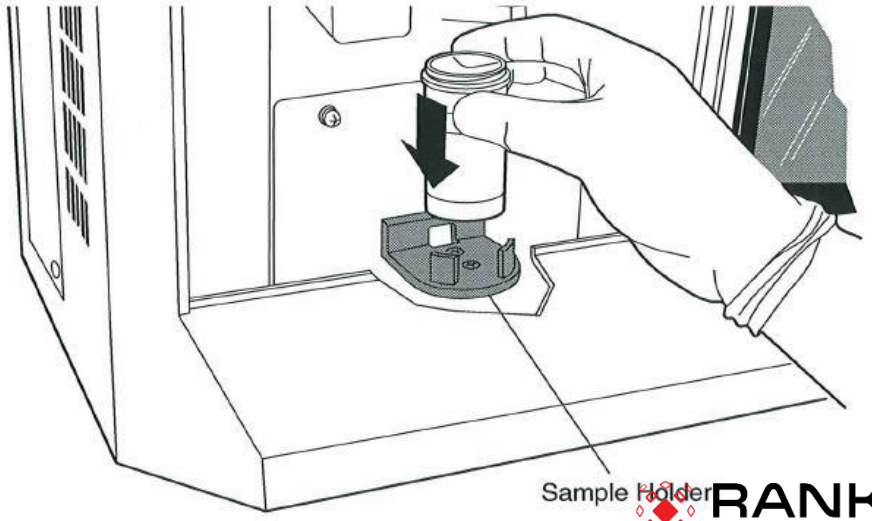
- Check the following before preparing a slide:
  - Waste Bottle - Be sure the fluid level is below the “MAX” fill line of the bottle.
  - Idle Mode - Confirm the instrument is powered on and in idle mode or menu mode
  - Filter seal O-rings - Make sure the O-rings of the filter cap are not dry, cracked or in need of lubrication.
  - Disposable laboratory gloves

Overview of Loading the ThinPrep 2000 Processor

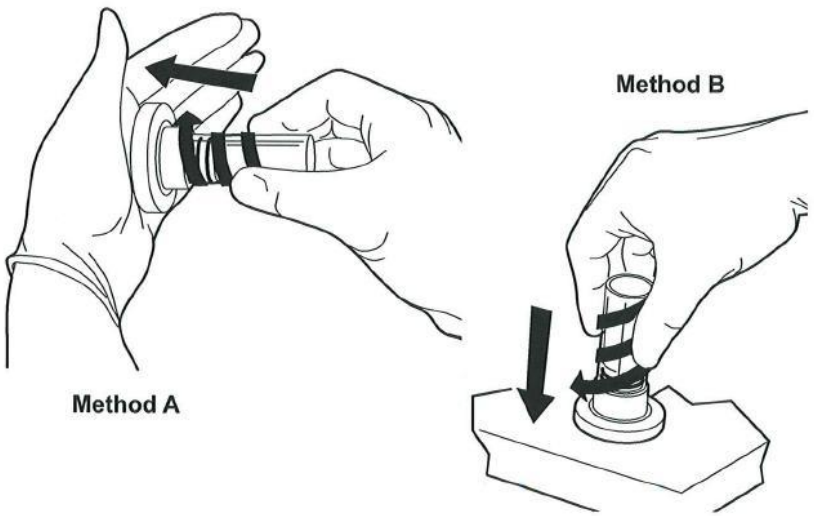


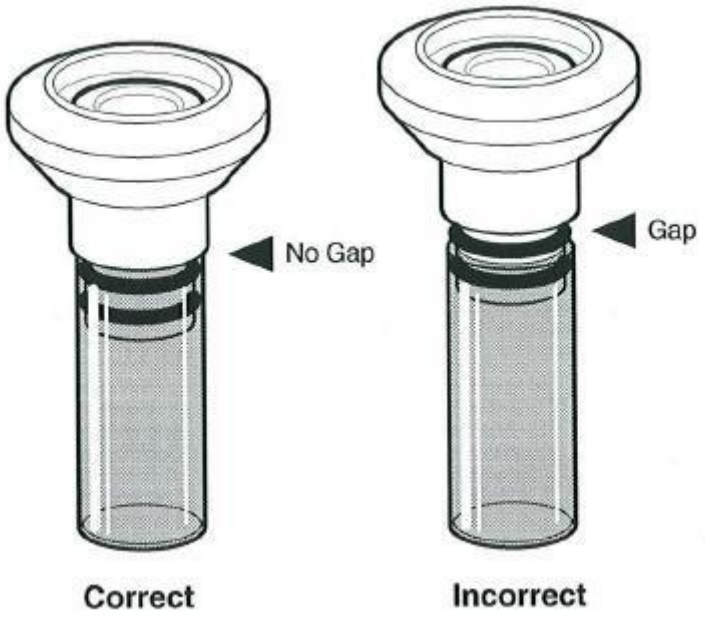
Loading the PreservCyt Sample Vial

1. Slide door open.
2. Confirm that the sample holder, fixative bath vial holder, and slide handler are all empty.
3. Remove the cap from the PreservCyt sample vial.
4. Place the PreservCyt sample vial into the sample holder until the bottom of the vial rests on the sample holder base.
5. The vial will remain loose until the process begins.

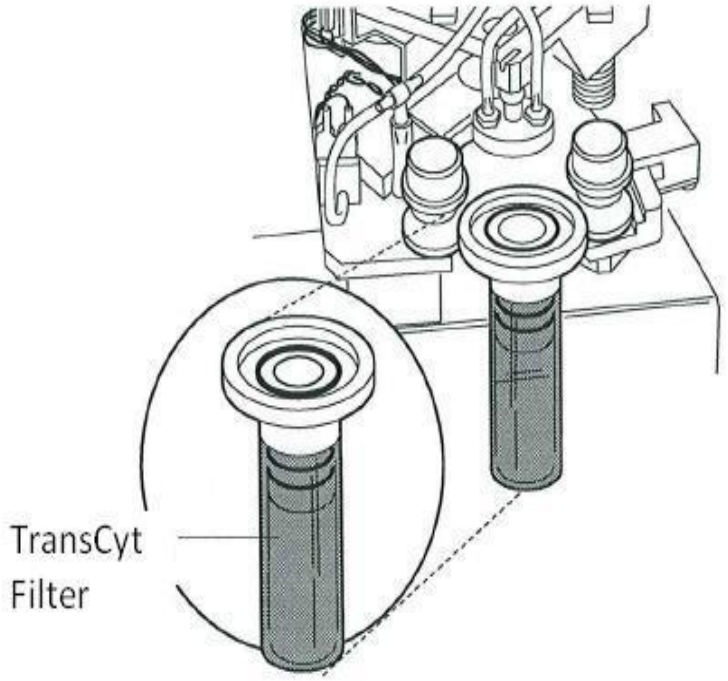


Loading the TransCyt Filter

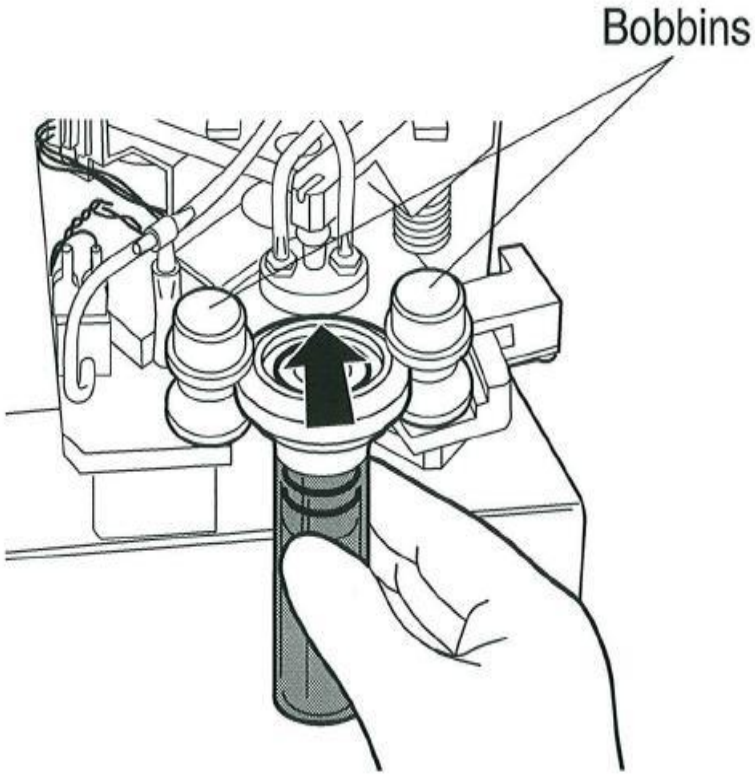




- Hold the filter assembly by the TransCyt Filter cylinder and place the angled edges of the filter cap against the two front bobbins

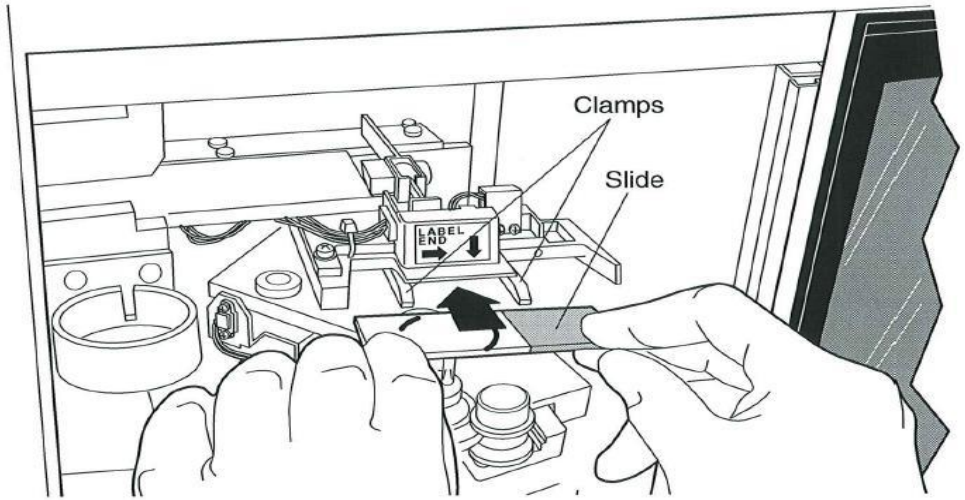


- Keeping the filter assembly level, push it straight into the instrument. The right bobbin will move to the right as the filter assembly is inserted. The filter is completely seated when the right bobbin moves back to the left and the two front bobbins hold the filter assembly in the processor.

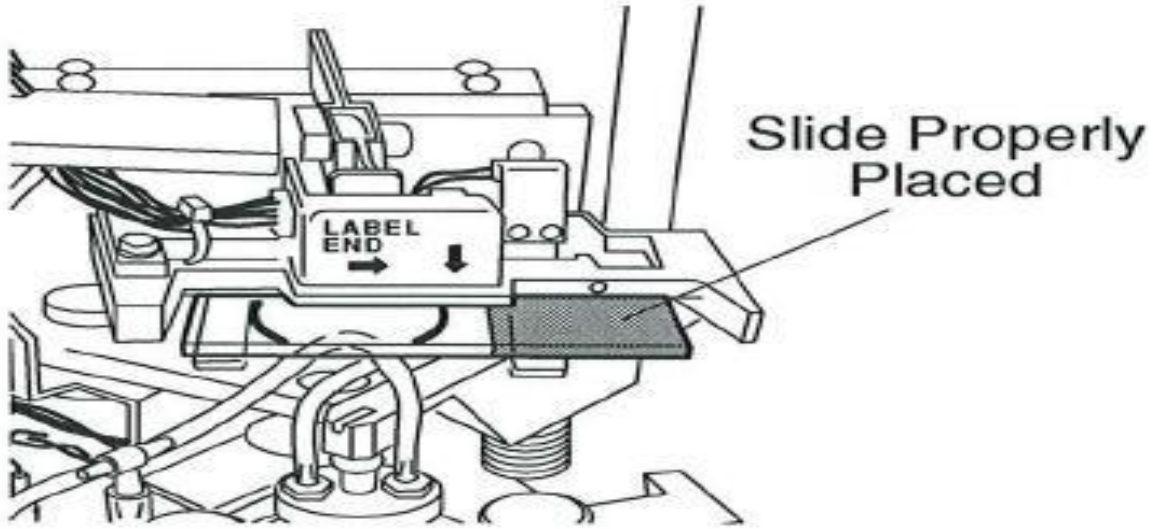


Loading the ThinPrep Microscope Slide

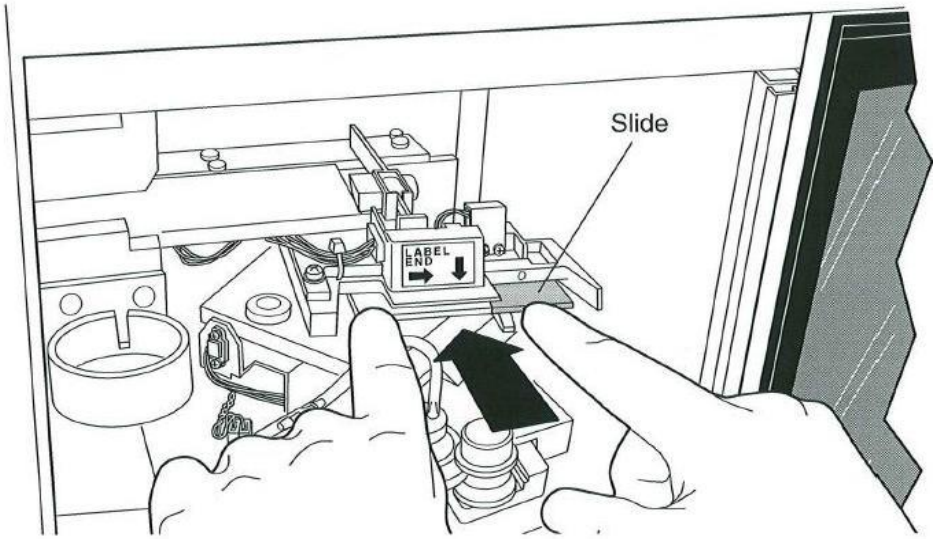
1. Label the ThinPrep Slide with the patient's identification information. Use the frosted area of the slide.
2. Using two hands, hold the slide by the two front corners with your index fingers and thumbs. Be sure not to touch the slide within the defined screening area. Place the label end to the right and facing down.
3. Insert the slide. Using the slide to push the spring loaded clamps down, insert the slide halfway under the upper guide block and over the spring-loaded clamps, then release the slide.



The slide should now rest *on top* of the two clamps and *under* the upper guide block.

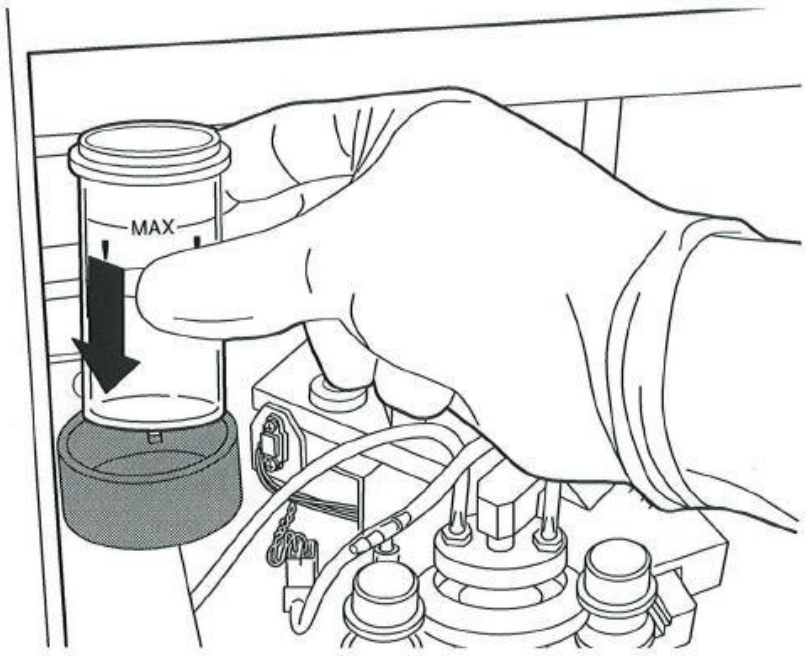


- Fully insert the slide by placing your index fingers against the exposed edge of the slide and push the slide in until it does not go any further.



Loading the Fixative Bath Vial

- Fill a fixative bath vial with standard laboratory fixative alcohol until the fluid level is between the “MIN” and “MAX” marks on the vial.
  - Change the contents of the fixative bath vial every 100 slides or daily, whichever occurs first.
- Place the fixative bath vial into the holder until the bottom of the vial rests on the base of the holder.



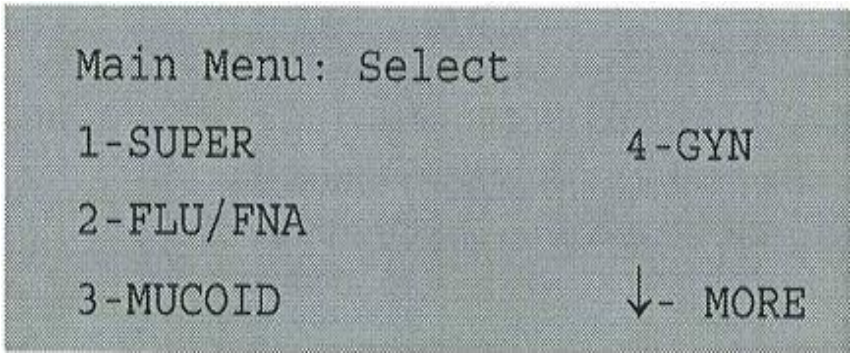
Close the Door

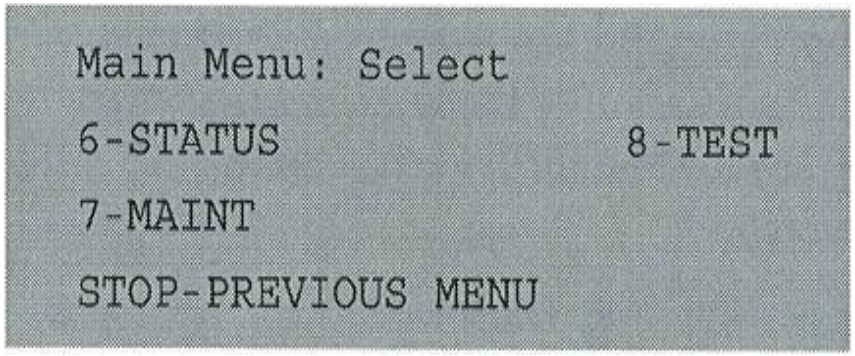
- The instrument will not operate if the door is open.
- The door must never be opened during instrument operation.
  - If the door is opened after processing has begins, the sequence will abort.

Selecting and Initiating a Sequence

- Two primary modes:
  - Sample Processing Sequences 1-5
  - Diagnostic 6-8

Main Menu





Key	Description
1	SUPERFICIAL SAMPLES Includes non-mucoid, superficial cell samples such as oral cavity samples, nipple secretions, skin lesions (Tzanck Test) and buccal samples
2	FLUIDS AND FNA SAMPLES Includes non-mucoid body cavity fluids and fine needle aspirates
3	MUCOID SAMPLES Includes sputum samples, bronchial brush and wash samples, and gastrointestinal samples.
4	GYNECOLOGICAL SAMPLES Includes cell samples from ectocervix and endocervix.
5	UROCYTE
6	STATUS
7	MAINTENANCE
8	TEST

- To initiate a sample processing sequence, simply press the key corresponding to the desired sequence.
- The sequence will begin immediately after the key is pressed.
  - If an incorrect sequence is selected, press the STOP key to abort the sequence.

  - At the end of the sequence, the display will return to the main menu.

Unloading the ThinPrep 2000 Processor

1. Slide the door to the right.
2. Remove the fixative bath vial containing the prepared slide from its holder. It is necessary to remove the fixative bath from the holder after each slide is processed.
3. Remove the prepared slide from the fixative vial and deposit the slide into a staining rack in a batch containing standard laboratory fixative.

4. Remove the TransCyt Filter from the filter cap.

Caution: To reduce the possibility of cross-contamination, use one of the following methods to remove the ThinPrep Pap Test Filter from the filter cap:

Method A:
Place a lint-free wipe around the ThinPrep Pap Test Filter to prevent contamination of your gloves while removing the filter assembly from the instrument and while separating the ThinPrep Pap Test Filter from the filter cap. Dispose of the lint-free wipe with the ThinPrep Pap Test Filter.

Method B:
Remove the ThinPrep Pap Test Filter from the filter cap and wipe off your gloves with lint-free wipe to remove any liquid or change your gloves after each slide preparation cycle.

5. Dispose of the used TransCyt Filter using appropriate laboratory procedures.

- **A TransCyt Filter must be used only once and cannot be reused.**

6. Remove the PreservCyt sample vial from the instrument and recap it firmly. Be sure to line up the torque line cap with the torque line on the vial.

7. Do not discard the sample vial until it has been determined that no additional slides are needed.

Interrupting the Slide Preparation Process

Ordinarily, the ThinPrep 2000 processor slide preparation process should not be interrupted, However, if it is necessary to stop processing for any reason, use the following procedure to ensure the slide is not contaminated with another specimen.

1. Press the STOP key and wait until the display reads, RECOVERY COMPLETE.
2. The ThinPrep Processor will halt the process with an audible tone and a message indicating that the STOP key was pressed will be displayed. The instrument will automatically recover and return the motors to their starting positions. The system will always attempt to return the cellular material on the filter back into the sample vial during error recovery.
3. Remove the fixative bath vial if it contains a slide, otherwise remove the ThinPrep Slide from the slide holder.
4. Remove the filter assembly
5. Remove the TransCyt Filter from the filter cap if it is wet or damaged.
6. Remove the PreservCyt Sample vial if it is not the correct specimen.

Status, Maintenance, and Test Screens

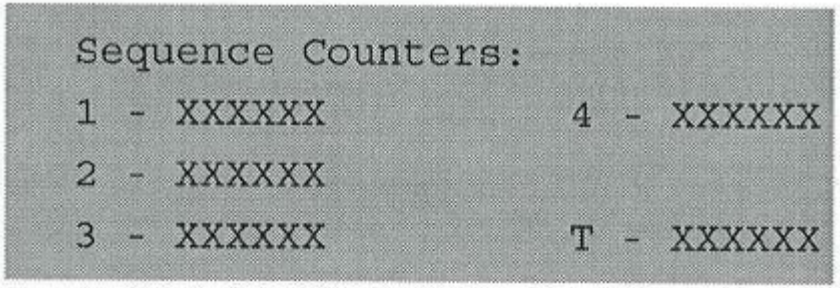
- 6 – Status

Pressing **6** from the Main Menu displays the following screen.

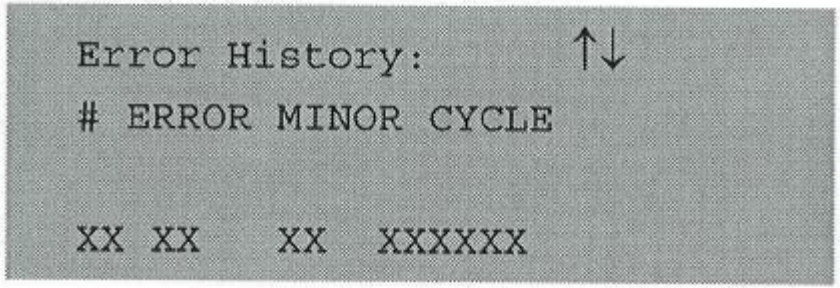
```
Status:
1 - COUNTERS
2 - ERROR HISTORY
3 - FIRMWARE VERSION
```

To return to the Main Menu, press STOP.

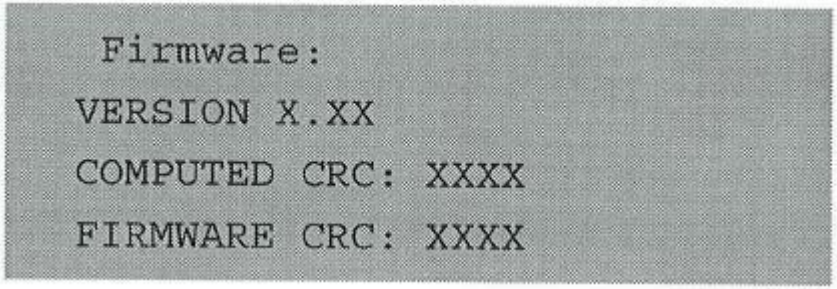
1. Counters –



2. Error History –



3. Firmware Version –



Press STOP to return to the Status Menu

Maintenance

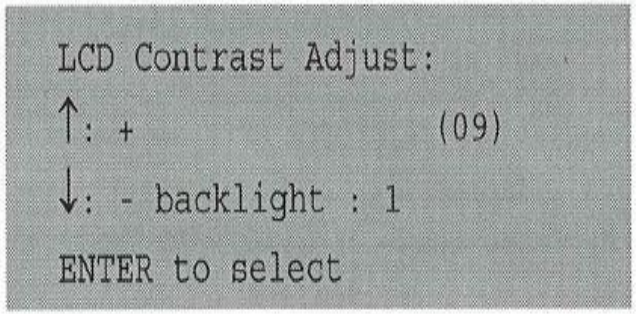
Pressing 7 from the Main Menu displays the following screen.

```
Maintenance:
1 - LCD ADJUST
2 - WASTE SYSTEM
3 - SERVICE MODE
```

To return to the Main Menu, press STOP. The processor must be completely empty of supplies before continuing with Maintenance.

1-LCD Adjust

1 – LCD Adjust:



Pressing 1 displays the LCD Contrast Adjust screen. A number is displayed in the parentheses from 00 to 15. Use the up and down arrow keys to adjust the contrast to an acceptable level and then press the ENTER key to save the change and to return to the Maintenance Menu.

2-Waste System

2 – Waste System:

```
Processing          17
Remove disposables
and vial. Press
ENTER when finished.
```

Pressing 2 initiates the waste system maintenance mode. It is critical to remove the fixative vial, filter, slide, and sample vial before continuing. After pressing ENTER to continue, three things occur:

- *Waste bottle vacuum vents to atmosphere* — The waste bottle vents to allow the operator to more easily remove the cap off the waste bottle for emptying of its contents. See Chapter 7, *Maintenance*, Section B.
- *Rotating plate in processor inverts* — The rotating plate inverts to allow the operator to more easily clean the underside of the cap seal. See Chapter 7, *Maintenance*, Section G.
- *Sample vial holder rises* — The sample vial holder rises to allow the operator to more easily clean under the holder. See Chapter 7, *Maintenance*, Section H.

When the maintenance operation is complete, the operator must press ENTER with the door closed to return to the Main Menu.

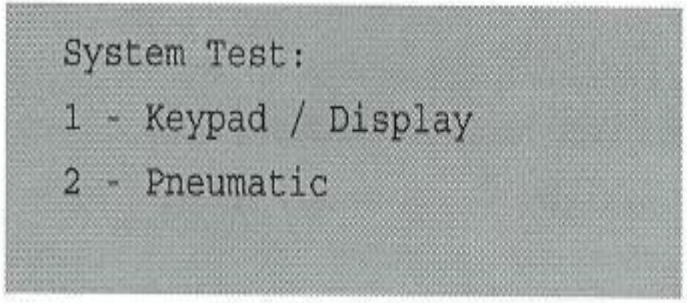
3- Service Mode

- Pressing 3 initiates the Service Mode Screen. This Service Mode is for service use only. Technical Service may ask you to access this screen during troubleshooting. To return to the Main Menu, press STOP.

Test

8 – Test:

Pressing 8 from the Main Menu displays the following screen. To return to the Main Menu, press STOP.



1 – Keypad / Display:

This test is used to confirm proper operation of the keypad and display. Pressing 1 initiates the Keypad / Display Test screen. Press all of the keys on the keypad and confirm that the corresponding character is changed on the display. Press the STOP key last to end the test. If any keys fail to respond, call Cytyc Technical Service.

2 – Pneumatic:

This test is used to confirm the proper operation of the entire pneumatic system. Cytyc recommends running this 5-minute test on a weekly basis. The results of this test may notify the operator to perform certain maintenance procedures or warn them that instrument service is required.

Pressing 2 prompts the user to load the sealed cylinder, which is the solid plastic model of the ThinPrep Pap Test Filter, into the instrument. Press ENTER to initiate the test. The test will automatically end if any errors occur and the operator will be notified of the area of concern. Once the problem has been addressed, it is necessary to run the test again to ensure proper operation. If no errors occur, the test will end with a message which indicates a successful test.