WellPrep Hely6 Processor Operator's Manual









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1. Overview of the WellPrep Hely6 Processor

1.1 Overview of WellPrep Hely6 Processor

WellPrep Hely6 Processor is a cell processor for liquid-based cytology. WellPrep Hely6 Processor is a device that automatically smears through centrifugation process using specially designed sample vial, Density Reagent Chamber, and Filter Paper.

When smearing using the WellPrep Hely6 Processor, various processes are performed through centrifugation to obtain a slide of a certain quality regardless of the sample state. That is, the cells in the sample vial are concentrated by primary centrifugation, and only the necessary cells are collected through the Density Reagent and transferred onto the slide. All of this is done through automatic centrifugation, which eliminates the need for a separate manual pretreatment. Therefore, a high quality slide can be obtained very conveniently regardless of the state of the specimen, thereby improving the convenience of work as well as the accuracy of the cell examination.

The WellPrep Hely6 Processor is used to screen for cells preserved in cell preservation solution. That is, the cells dropped from various organs are plated on a slide glass and used to diagnose precancerous cells, abnormal cells, and cancer cells. In addition to gynecological samples, FNA, sputum, urine, and fluid samples can be processed.



<Photo 1> WellPrep Hely6 Processor

1.2 Overview of the WellPrep Hely6 Operation

WellPrep Hely6 Processor performs various smearing operations in the process of centrifugation with Specimen Vial containing specimen, Density Reagent Chamber containing Density Gradient Reagent, and Filter Paper and Slide in order.



<Photo 2> WellPrep Hely6 Process Operation Process

(1) 1st Centrifugation for Cell Condensation : The first centrifugation process collects the cells in the Specimen Vial down the vial. At this time, debris is filtered through the mesh. The cells aggregated through the first centrifugation are transferred to the Density Reagent Chamber.

(2) 2nd Centrifugation for Cell Separation : The cell pellet collected in the first centrifugation process is transferred to the Density Reagent Chamber, and the second centrifugation separates the light and heavy cells by the Density Reagent in the Density Reagent Chamber. As a result, the cells needed for the examination settle down to the bottom of the Density Reagent Chamber and light white blood cells, red blood cells and red blood cell debris float above the Density Reagent Chamber.

(3) 3rd Centrifugation for Cell Sedimentation onto the Slide : After the second centrifugation, the cell pellet settled under the Density Reagent Chamber is transferred to the slide and smeared.



1.3 Specification of the WellPrep Hely6 Processor

WellPrep Hely6 Processor is a unique system that provides a simple liquid cell smearing process. The system can handle 70 slides / hour for each type of process, depending on the customization.

1.3.1. Features

- Provides a simple and easy smearing process
- High performance with 70 processes per hour at low cost
- Automated system with minimal user manual
- Variety of smear conditions according to various samples
- Monitor the sample processing status on the LCD screen

1.3.2. Specifications

- Model : WellPrep Hely6 Processor
- Throughput : 70 slides/hour
- Size : 460 X 520 X 340(h)mm
- Weight : 35kg
- Electric Voltage and Frequency : 100 ~ 240 V, 50 ~ 60 Hz
- Power : Up to 500 Watts
- Fusing : Overcurrent Protection Device (250V, 5A)
- Operating Temperature : 18-40 °C
- Operating Humidity : 20%~80%



1.3.3 Size and Appearance



1.4 Warranty Service

Bionit Inc. guarantees the purchaser that there is no defect in manufacturing technology and equipment for one year from the date of purchase.

If any product is found to be defective at any time during the limited warranty period, Bionit Inc. will replace or repair the product. The limited warranty does not cover damage due to improper installation, improper connection, accidents, misuse, abuse, negligence, abnormal operating conditions or modification of parts of the device.

Contact your local dealer for claims under warranty. In order to send the device directly to Bionit Inc., you must send a copy of the invoice and a description of the claim.



1.5 Handling of the Equipment

General Cautions

- Store specimen at room temperature (15 ~ 30 °C).
- Specimen containing cells should be refrigerated (4 °C). In particular, when reinspection is required after the inspection, be sure to refrigerated.
- Check the expiration date before use.
- Review the MSDS in advance and wear the necessary protective equipment.

♦ Cautions at Installation

- Avoid the place with high temperature and humidity and install in the place with good ventilation.
- Install it horizontally where there is no vibration at a distance of 30 cm from the wall.
- For safety reasons, avoid places with inflammables and explosive hazards.
- Make sure to check the rated voltage and connect according to the capacity.
- Do not install in places with high voltage fluctuation rate (allowable voltage fluctuation rate: ± 10%)
- Use a grounding outlet for the outlet.
- When carrying and moving the product, it must be carried by two or more people.
 Protect hands by using gloves.

• Cautions at Operations

- Do not use at room temperature below 2 $^\circ\!\!\mathbb{C}$, above 40 $^\circ\!\!\mathbb{C}$ or above 80% of humidity.
- There is a risk of electric shock. Do not plug or unplug the power cord with wet hands.
- If the temperature changes abruptly around the device, moisture may be generated inside the product, which may cause the device to break down.
- The power should be single phase, 100 ~ 240V, 50 ~ 60Hz, and the power cord provided by the company should be used.

♦ General Cautions

- Use neutral detergent without cleaning with solvent or thinner.
- Be sure to use the designated product (product only for WellPrep Hely6 Processor).
- In case of abnormal smell or smoke or error during use, cut off the main power and contact our customer service center for safety.
- Except for service personnel authorized by our company, parts replacement,



repair, and alteration are prohibited.

♦ Caution Symbols





2. Installing of WellPrep Hely6 Processor

2.1 Preparation of Installing

WellPrep Hely6 Processor is a cell processor for liquid-based cytology. Therefore, the equipment should be installed by a person who is professionally trained in Bionit Inc. After the equipment has been installed by an expert, it must be correctly trained and used.

♦ Installing / Education

WellPrep Hely6 Processor requires service and guidance from our staff or personnel who have completed installation training. Once the installation is complete, provide the MANUAL to the customer and provide operation and operation training.

• Packaging / Delivery

Check the package for damage before installation and if damaged, report it to the shipper and our service department immediately.

♦ Installing of the Equipment

Fix the foot after installing the equipment horizontally with the installation space secured. Connect the power cord provided with the equipment.

♦ Table

The table needs 700mm in length and over 5000mm in length because it needs to secure the space for installation and discharging of the main body.

2.2 Wiring of the WellPrep Hely6 Processor

Install WellPrep Hely6 Processor on the correct table and connect to the equipment using the power cable for the WellPrep Hely6 Processor.

2.3 Connecing the Power to WellPrep Hely6 Processor

Connect the dedicated power cable to the WellPrep Hely6 Processor correctly and press the power on button to supply power.

Well**Pr**ểp

2.4 Consumables for WellPrep System

2.4.1 Consumables for WellPrep System

All consumables used in the WellPrep Hely6 Processor are disposable and cannot be reused. The consumables used in the WellPrep Hely6 Processor are as follows.

- WellPrep CytoGyn : Cell Preservative Solution for Gynecologic Sample.
- WellPrep CytoNGyn : Cell Preservative Solution for Non-Gynecologic Sample such as FNA, Body Fluid, Urine and Sputum
- WellPrep CytoTrans : Cell Transportation Media
- WellPrep CytoHemo : Hemolysis Solution
- WellPrep CytoMuco : Mucolysis Solution
- WellPrep CytoDensy : Density Reagent Solution
- WellPrep CytoPsy : Biopsy Container
- WellPrep CytoPAP-HX : Hematoxylin Solution for PAP Stain
- WellPrep CytoPAP-EA50 : EA50 Solution for PAP Stain
- WellPrep CytoPAP-OG6 : OG6 Solution for PAP Stain
- WellPrep CytoMount : Mounting Media
- WellPrep Coating Slide : Coating Slide
- WellPrep Filter Paper : Filter Paper
- WellPrep Cover Glass : Cover Glass
- WellPrep Density Reagent Chamber : Density Reagent Chamber
- WellPrep DRC Opener : Density Reagent Chamber Opener
- WellPrep Cyto Brush : Cyto Brush



No.	Model Name	Intended use and Specification	Photo
1	WellPrep Hely6 Processor	Sample Process - 6 ea/operation - 35kg - 46x52x34 cm	
2	WellPrep CytoGyn	Cell Preservation for Gynecological Specimen - 10ml	Terrente Contraction
3	WellPrep CytoNGyn	Cell Preservation for Non- Gynecological Specimen - 10ml	Hanning Contraction
4	WellPrep CytoTrans	Cell Transportation Media - 25ml	
5	WellPrep CytoHemo	Hemolysis Solution - 1000ml	
6	WellPrep CytoMuco	Mucolysis Solution - 1000ml	
7	WellPrep CytoDensy	Density Reagent - 2ml	



8	WellPrep CytoPsy	10% Formaldehyde Solution 10ml for Biopsy - 10ml	
9	WellPrep CytoPAP-HX	Harris Hematoxylin Solution for Papanicolaou Stain - 500ml	PRPANICOLAOU STAIN
10	WellPrep CytoPAP- EA50	EA-50 Solution for Papanicolaou Stain - 500ml	FRFANICOLADU STAIN
11	WellPrep CytoPAP- OG6	Orange G-6 Solution for Papanicolaou Stain - 500ml	Phinical nau Stain
12	WellPrep CytoMount	Mounting Media for Cover Slips - 100ml	
13	WellPrep Coating Slide	Coating Slide - 25.4 x 76.2 x 1 mm	
14	WellPrep Filter Paper	Filter Paper - 25.4 x 76.2 x 1 mm	
15	WellPrep Cover Glass	Cover Glass - 22 x 40 x 0.1 mm	



16	WellPrep Density Reagent Chamber	Density Gradient Reagent Chamber - 2ml	
17	WellPrep DRC Opener	DRC Opener	
18	Cyto-Brush	Cervical Brush - CYB-1 : 12.7 x 30 mm - CYB-2 : 20.7 x 32 mm - CYB-3 : 12.7 x 27 mm - CYB-4 : 18.1 x 35 mm	

3. Cell Preservative Solutions and Reagents

3.1 Cell Preservative Solutions

3.1.1 Handling of Cell Preservative Solutions

There are two kinds of cell solution. WellPrep CytoGyn is a cell preservative solution for preserving gynecological specimens. WellPrep CytoNGyn is a cell preservative solution for preserving samples such as FNA, Body Fluid, Urine, and Sputum.

When testing with the WellPrep system, cell preservative solutions such as WellPrep CytoGyn or WellPrep CytoNGyn should be used. Not WellPrep solutions from water or alcohol must not be used.

Cell preservative solutions are stored at room temperature (15 °C \sim 30 °C). In addition, do not use the cell preservative solution beyond the expiration date. In principle, the cell-preservative solution containing the sample should be refrigerated.

Cell preservative solution or samples must be moved with the cap closed correctly.

3.1.2 MSDS for Cell Preservative Solutions

♦ Hazard Statements

- H226 flammable liquids and vapors
- H315 Causes skin irritation.
- H319 Causes serious eye irritation.
- H361 Suspected of damaging fertility or the unborn child
- H371 May cause damage to organs (nervous system, kidneys, respiratory system, liver).

Prevention

- P201 Obtain special instructions before use.
- P202 Do not handle until all safety precautions have been read and understood.
- P210 Keep away from heat / sparks / open flames / hot surfaces.-No smoking.
- P233 Keep container tightly closed.
- P240 Container and receiving equipment to be bonded or grounded.



- P241 Use explosion-proof electrical / ventilating / lighting / equipment.
- P242 Use only non-sparking tools.
- P243 Take precautionary measures against static discharge.
- P280 Wear protective gloves / protective clothing / eye protection / face protection.
- P264 Wash thoroughly after handling.
- P260 Do not breathe (dust, fume, gas, mist, vapor, spray).
- P270 Do not eat, drink or smoke when using this product.
- P271 Use only outdoors or in a well-ventilated area.

♦ Correspondence

- P303 + P361 + P353 If on skin (or hair): Take off all contaminated clothing.
 Rinse skin with water / shower.
- P332 + P313 If skin irritation occurs: Get medical advice / attention.
- P362 + P364 Take off contaminated clothing and wash before reuse.
- P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes.
 Remove contact lenses if possible. Keep washing.
- P337 + P313 If eye irritation persists, get medical advice / attention.
- P308 + P311 If exposed or concerned: Get medical attention.
- P370 + P378 In the event of fire, use dry chemical, CO2 extinguishing media.

Storage

- P403 + P233 Store in a well-ventilated place. Keep container tightly closed.
- P235 Keep cool.
- Store in a storage area with P405 lock.

♦ Disposal

 P501 Dispose of contents and container (according to the description in the related regulation).

3.2 Transportation Media

WellPrep CytoTrans is used to move or preprocess samples in a short time. For example, in the case of FNA sample, if the sampled specimen contains a lot of blood or mucus, the sample is first put in the transportation media (WellPrep CytoTrans), and then hemolysis or mucus is removed, and only the cells are collected and put into the cell preservation solution (WellPrep CytoNGyn). In addition, in the case of urine specimens, when the sampled urine specimens cannot be processed immediately, the urine specimens can be transported after being placed in the transportation media (WellPrep CytoTrans). In case



of other blood-rich samples or high-mucus samples, put the sample in the transportation media (WellPrep CytoTrans), and if there is too much blood, hemolysis is performed with WellPrep Hemolysis Solution. Put it in.

Transportation Media should be stored at room temperature (15 °C to 30 °C). Also, don't use transportation media that has expired. Transportation media containing specimens should be refrigerated in principle.

The transportation media containing the sample must be moved with the cap closed correctly.

3.3 Density Gradient Reagent

Density Gradient Reagent (WellPrep CytoDensy) is used for centrifugation of cells. Density Gradient Reagent has constant density and viscosity, so it is possible to separate heavy cells and light red blood cells, white blood cells and mucus by centrifugation with sample in Density Gradient Reagent (WellPrep CytoDensy).

Density Gradient Reagent is supplied in the WellPrep DRC Chamber. When working with WellPrep Hely6 Processor, install WellPrep DRC Chamber provided in the correct direction.

Density Gradient Reagent Chamber is a disposable, so one Density Gradient Reagent Chamber is used for one sample and cannot be reused.

Store the Density Gradient Reagent at room temperature (15 ° C to 30 ° C). In addition, do not use expired Density Gradient Reagent.

3.4 Lysis Solutions

When using the WellPrep Hely6 Processor, two Lysis Solutions are provided for sample pretreatment.

WellPrep Hemolysis Solution (WellPrep CytoHemo) is used to remove red blood cells when the sample contains a lot of blood. After treatment with WellPrep Hemolysis Solution, remove red blood cells and smear according to WellPrep pretreatment method.



WellPrep Mucolysis Solution (WellPrep CytoMuco) is used to remove mucus if the sample contains a lot of mucus. After treatment with WellPrep Mucolysis Solution according to WellPrep pretreatment method, mucus is removed and smeared.

3.5 Others

WellPrep supplies WellPrep CytoPAP-HX, WellPrep CytoPAP-EA50, WellPrep CytoPAP-OG6, etc. used for PAP staining. PAP Stain method using PAP Stain Reagent provided by WellPrep is described in this manual.

In addition, WellPrep CytoMount, which is used to seal the slide for long term storage, is used to bond the cover glass to the slide. Coverslipping method is performed according to the method described in this manual.

4. Operating Instruction

4.1 Preparation of The Equipment

4.1.1 Power On

- Place the device on a sturdy table parallel to the ground before operation. Using a tilted device can reduce the accuracy of the process.
- Make sure the power switch on the side of the device is set to "OFF".
- Connect the power cable to the power port on the back of the device.
- Turn on the "On" switch and check that the LCD is turned on.

4.1.2 User Interface Module

The user module of the device has an LCD display and six buttons. This module provides simple and easy operation between the user and the device.

4.1.3 Display

WellPrep Hely6 Processor uses a 4x20 LCD display module. The display is 4 lines each and can hold 20 characters.





4.1.4. Buttons

The main buttons used to operate the equipment are as follows.



4.2 Operation of the Equipment

4.2.1 Menu Move

The menu of WellPrep Hely6 Processor is Select, Edit, Home, Setting. To select the menu



Select Menu is a menu to select a mode to apply. In the case of obstetrics and gynecology specimens, "Mode A" should be selected.

4.2.2 Menu Select

Each mode is set to the optimum condition according to various specimen. If there are many cells in the sample, if there are few cells in the sample, etc., various parameter values are adjusted for each mode to select the appropriate one.

First, the initial state of the LCD screen of the WellPrep Hely6 Processor is shown below.



Use



Pressing this button changes to the Select mode. You will see a screen where you can select various modes as shown below.

->Mode A	
Mode Mode	
Mode	D

to select among various modes. Move the cursor to the desired mode

and press to select the mode. For example, if you select Mode A, the message shown below will appear.



4.2.3 Edit Mode

Each mode is for storing and utilizing various conditions according to various samples. It is very convenient to save smearing condition of various condition for each mode and use it according to the sample. In other words, in case of Mode A, the conditions for Gyn



sample, in Mode B, for Urine, and in Mode C, for FNA are stored. It is convenient to apply optimal smearing condition.

The values saved in each mode can be edited as follows. First move the cursor to Edit and

to enter Edit mode.

press





4.2.4 Return Home Position

If you have a problem while operating the WellPrep Hely6 Processor and want to reset the location of the device, select Home as shown below.



When the initialization is completed, the following message is displayed.





4.2.5 Setting Machine Parameters

During the operation of the WellPrep Hely6 Processor, various position and speed adjustments are made in the setting mode. First move the cursor to Setting and press



Select Edit	
Home Setting	

Then, various variable values that can be edited appear as shown below.



4.3 Preparation of Specimen

To smear the specimen, install Specimen Vial, DRC (Density Reagent Chamber), DRC Opener, Filter Paper, and Slide from the inside as shown below.



Specimen vial should be installed with the cap facing the center and DRC should be placed with the pipette facing the vial. The DRC Opener must also be positioned so that Pipette faces the DRC.



Set the consumables in the order shown below. First, put the cap of the vial in the direction of the center and insert the specimen vial vertically downward.



Secondly, insert the coating slide with the coating side facing inward. At this time, make sure that the contents of the sample to be tested are written correctly. A slide containing



the same ID information as the sample can be inserted into the same slot as the sample.



Third, put the filter paper in front of the slide.



Insert Filter Paper and Opener. The opener should be placed with the pipette direction towards the center.



Finally, put a DRC (Density Reagent Chamber). At this time, the cap of DRC should be placed toward the center.



4.4 Balance When Sample Setting

Since the WellPrep Hely6 Processor is a centrifugal smearing device, it is very important to balance the sample when it is mounted on the device. The WellPrep Hely6 Processor can be equipped with a total of six specimens, but two, three and four can be loaded in a balanced manner. If one or five specimens are loaded, they may be out of balance,



resulting in errors during operation.



When mounting two specimens, mount the specimen diagonally as shown below.

When mounting three specimens, install them so that they are balanced by maintaining them at an angle of 120 degrees to each other as shown below.



When four specimens are mounted, they are mounted in an X shape as shown in the figure below so that they are balanced.





4.5 Smearing Operation

When everything is ready, press to start smearing. Depending on the selected mode, various working conditions are operated according to the preset values, and smearing is performed.

If the plated slide is left in the air for a long time, degeneration may occur in the cells. After collecting the slide, remove it from the specimen vial inside and remove it in the order of DRC, DRC Opener, etc.

After all the work is done and the work is done, clean the inside of the equipment with a tissue or cloth soaked in 75% alcohol for the next day's work.

4.6 Removing the Specimen after Smearing Operation

After all the smearing is done, the slide is first removed from the instrument. At this time, the cells are attached to the slide, carelessly may affect the cells attached to the slide. Therefore, when the slide is separated from the WellPrep Hely6 Processor, remove the slide, the filter paper, and the opener by lifting them up in the vertical direction as shown below. If the coating slide, filter paper and opener are separated from the equipment, carefully separate the coating slide from the filter paper and opener and put them in 95% alcohol.



If the Coating Slide, Filter Paper and Opener were separated from the WellPrep Hely6 Processor, then the Specimen Vial was removed from the instrument. At this time, grasp both ends of Specimen Vial and lift it up in the vertical direction to separate.



Finally, hold the DRC at both ends and separate it vertically upwards.





If the slide is left in the air for a long time, the cells may be denatured. When the smearing is completed, the slide is first removed from the equipment and put in 95% alcohol. After collecting the slide, remove it from the specimen vial inside and remove it in the order of DRC, DRC Opener, etc.

After all the work is done and the work is done, clean the inside of the equipment with a tissue or cloth soaked in 75% alcohol for the next day's work.



5. Maintenance

5.1 Maintenance Cycle

When using the WellPrep Hely6 Process, maintain the equipment at the following intervals.

Cycle	Maintenance
Every Patch	- Empty each tray at the start of each batch
Deily	- Clean the each tray and bath of the equipment
Daily	- Clean slide holder
Weekly	- Clean the bath of the equipment with clean tissue or clothe with alcohol
As Needed	- Clean the touch screen
	- Clean the inside and outside of equipment

5.2 Daily Maintenance

After every day's work, clean the area inside the machine with a cloth moistened with alcohol or a tissue. Also, clean the inside of the tray where the sample and the DRC were placed, including the slide holder, with a cloth moistened with alcohol or a tissue.

5.3 Weekly Maintenance

After weekly work, clean the inside and outside of the equipment with a cloth or tissue moistened with alcohol. In particular, spray alcohol around the slide holder and clean it with a cloth or tissue.



6. Troubleshooting

6.1 Troubleshooting Problems During Operations

In case of colliding with specimen or consumables wrongly during the smearing operation,

if the collision occurs due to the rotation, press to immediately start the operation of the equipment. Or cut off the power so that the equipment can stop immediately.

When Jamming occurs due to abnormal operation of the equipment, press Home to move to the initial position of the equipment.

6.2 System Troubleshooting

Refer to the table below for Error occurred during system operation.

Error Message	Troubleshooting
Homing error	 Home position error. Please select "Home" menu. Or shout down the system and reboot.

7. Stain and Coverslipping Method

7.1 Standard PAP Stain Protocol

The completed slides were fixed in 95% alcohol for 30 minutes before PAP staining. The standard PAP stain staining protocol recommended by the WellPrep system is shown in the table below.

No	Reagent	Operation
1	Water	Tap Washing
2	Harris's Hematoxylin	1 min Dip
3	Water	Tap Washing
4	1% HCL Alcohol	10 times Dip & Out
5	Water	Tap Washing
6	1% Ammonia	10 times Dip & Out
7	Water	Tap Washing
8	95% Alcohol	10 ~ 15 times Dip & Out
9	95% Alcohol	10 ~ 15 times Dip & Out
10	OG6	6 min Dip
11	95% Alcohol	10 ~ 15 times Dip & Out
12	95% Alcohol	10 ~ 15 times Dip & Out
13	EA50	6 min Dip
14	95% Alcohol	10 ~ 15 times Dip & Out
15	95% Alcohol	10 ~ 15 times Dip & Out
16	100% Alcohol	10 ~ 15 times Dip & Out
17	100% Alcohol	10 ~ 15 times Dip & Out
18	Xylene	10 ~ 15 times Dip & Out
19	Xylene	10 ~ 15 times Dip & Out
20	Mounting	



7.2 Standard Coverslipping Protocol

Encapsulation is in accordance with each method. However, when using the WellPrep system, use the WellPrep CytoMount solution provided by WellPrep and use the WellPrep Cover Glass.

WellPrep Cover Glass comes in two types, 24mm x 40mm or 24mm x 50mm, and one of two types is used depending on the situation.



8. Service Information

The service for WellPrep Hely6 Processor proceeds according to the information below.

- Company Name : Bionit Inc.
- Address : 118, 20, Gangnamseo-ro, Giheung-gu, Yongin-si, Gyeonggi-do, Korea, 16977
- Tel: +82-31-309-9009
- FAX : +82-31-309-9005
- E-mail : info@bionit.co.kr



9. Ordering Information

Using the WellPrep Hely6 Processor, order the necessary parts using the information below.

- Company Name : Bionit Inc.
- Address : 118, 20, Gangnamseo-ro, Giheung-gu, Yongin-si, Gyeonggi-do, Korea, 16977
- Tel: +82-31-309-9009
- FAX : +82-31-309-9005
- E-mail : info@bionit.co.kr

<Table> Service Item Information

Item	Description	Order Number









Bionit Inc.

118, 20, Gangnamseo-ro, Giheung-gu, Yongin-si, Gyeonggi-do, KOREA, 16977 Tel : +82 (0)31-309-9009 Fax : +82 (0)31-309-9005 www.bionit.co.kr, info@bionit.co.kr