HORIBA
Medical

HEMAPREP®

Blood Spreading System

User Manual

Ref: RAB316AEN

HEMAPREP®

User Manual

CE IVD

HORIBA ABX SAS
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Ref: RAB316AEN

HEMAPREP®

Contents

Foreword

1. Revisions

Reference	Internal Reference	Document Date Issued
	RAB316AEN	November 2016

This document is only available online at www.horiba-abx.com/documentation.

2. Legal Information

2.1. Declaration of Conformity

This product complies with the Standards and Directives named in the Declaration of Conformity.

The latest version of the EC Declaration of Conformity for this product is available on www.horiba-abx.com/documentation.

2.2. Notice of Liability

The information in this manual is distributed on an "As Is" basis, without warranty. While every precaution has been taken in the preparation of this manual, HORIBA Medical will not assume any liability to any persons or entities with respect to loss or damage, caused or alleged to be caused directly or indirectly by not following the instructions contained in this manual, or by using the hardware products described herein in a manner inconsistent with our product labelling.

2.3. Trademarks

Other product names mentioned within this publication may be trademarks or registered trademarks of their respective owners.

2.4. Graphics

All graphics or photographs are for illustration purposes only and are not contractual.

2.5. Document Symbols

To alert the operator of potentially hazardous conditions, symbols described in this chapter are provided wherever necessary throughout the manual.

Emphasizes information that must be followed to avoid hazard to either the operator or the environment, or both.

Emphasizes information that must be followed to avoid possible damage to the system.

Emphasizes information that can be helpful to the operator before, during or after a specific operational function.

Gives a summary of what can be achieved if the task is performed.

2.6. Typographical Conventions

Before you start using this documentation, you should become familiar with the following typographical conventions.

More information on www.horiba-abx.com/documentation.

External links can be used to retrieve information from a web site.

Related information:
- To Calibrate the System, p.24
- To Clean the Spreader Blades, p.26

The *Related information* box provides clickable internal links to navigate throughout the user manual.

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Introduction

1. Warning and Precautions

This system must be operated as instructed in the user manual. Any other use might compromise system integrity and might be hazardous for the operator.

This system complies with Standards and Directives named in the Declaration of Conformity. The latest version of the Declaration of Conformity for this system is available online at www.horiba-abx.com/documentation.

- The accessories stipulated by HORIBA Medical have been validated in accordance with the European Directive for *in vitro* medical devices (98/79/EC).
- The use of some other accessories may place the performance of the system at risk, thus engaging user responsibility. In this case, HORIBA Medical takes no responsibility for the system nor for the results rendered.
- Disposable gloves, eye protection and lab coat must be worn by the operator.
- Local or national regulations must be applied in all the operations.

1.1. Limited Warranty

The duration of warranty is stipulated in the Sales conditions associated with the purchase of this system. To validate the warranty, ensure the following is adhered to:

- The system is operated under the instructions of this manual.
- Maintenance must be done by recommendation from HORIBA Medical using only approved spare parts.
- The system is operated according to HORIBA Medical recommendations.
- Proper tools are used when maintenance or troubleshooting operations are performed.

If this system has been supplied to you by anyone other than HORIBA Medical or an authorized representative, HORIBA Medical cannot guarantee this product in terms of specification, latest revision and latest documentation. Further information may be obtained from your authorized representative.

1.2. Operational Precautions

- Gently manipulate the front lever.
- When using frosted slides, make sure frosted portion is facing front. If not, spreader blades come into contact with frosting and become nicked.
- Clean the spreader blades between each operation especially if an excess of blood was applied on the slides, to prevent carry-over.
- Carefully handle the slides.

Related information:
- To Clean the Spreader Blades, p.25

1.3. Biological Hazard

Consider all specimens that contain human specimen extracts as potentially infectious! Use established, good laboratory working practices when handling specimens. Wear protective gear, gloves, lab coats, safety glasses and/or face shields, and follow other biosafety practices as specified in OSHA Blood borne Pathogens Rule (29 CFR part 1910. 1030) or equivalent biosafety procedures.

All accessible surfaces of the system can be potentially contaminated by human specimens. Disposable gloves and lab coat must be worn by the operator. Local and national regulations must be applied in all the operations.

1.4. Graphics and Symbols

IVD — *In Vitro* Diagnostic medical device

CE — This product conforms to the EC Directives named in the Declaration of Conformity

Manufacturer

Biological hazard

Packaging recycling mark

Consult Instruction for Use

2. Operational Conditions

2.1. Environmental Protection

Used Accessories and Consumables Disposal

Disposable used accessories and consumables must be collected by a laboratory specialized in elimination and recycling of this kind of material according to the local legislation.

System Disposal

This product should be disposed of in accordance with local and applicable country specific standards.

If any doubt, please contact your local representative.

2.2. Installation

Package content:

- HEMAPREP
- Spreader blades

Only HORIBA Medical approved accessories should be used with the HEMAPREP.

2.3. Package

Factory package of the system HEMAPREP and its implements consists of firm corrugated cardboard and polyethylene foil. Package protects the system and its implements from adverse factors of outside environment.

The system must be transported in its original factory package.

After unpacking, we recommend you to:

- Visually check the system
- Check the spread quality on first using

3. Labels and Connections

3.1. Serial Number Label

The serial label is located below the system.

3.2. Warnings and Biological Hazards Labels

Warning! Biological hazard

Front of the system
Risk: the specimens containing human specimen extracts are potentially infectious; all accessible surfaces of the system can be potentially contaminated.
How to avoid the risk: wear suitable protective gloves and handle glasses carefully.

Specifications

1. Intended Use

The HEMAPREP is a mechanical system designed to emulate the manual method of preparing peripheral blood films by the wedge technique.

The system was created for both stationary or portable use.

- As stationary use, it is valuable for preparations in laboratories or at fixed locations.
- As portable use, it is valuable for specimens preparation at patients bedside.

You can use both frosted end and clear slides.

2. Principles of Operation

The system is lever operated and does not require an external power source or battery.

1. Glass spreader blades are mechanically brought into contact with the drop of blood.
2. The system stops to allow the blood to moisten the spreader blades.
3. The spreader blades gently pull the blood along the slide at a predetermined angle and preselected speed.
4. The speed control which is achieved by an air-operated piston, gently delivers the blood in the standard wedge configuration.

3. Performance Characteristics

The HEMAPREP can achieve reproducible smears with ample working area, good distribution and minimization of trauma because the smearing action is automatically controlled.

It produces borders along the edges of the slide which facilitates inspection of these areas when used in accordance with these instructions.

The smears length and thickness are related to the hematocrit, the quantity of blood used and the spreader blades speed.

As the system delivers at a constant rate, the monolayer of long and short smears is generally similar.

Workflow

1. General Recommendations

1.1. Blood Sample Collection

Accepted types of blood

The system accepts both fresh blood and blood collected in anti-coagulant as EDTA.

We recommend you to perform operation as soon as possible after collection. EDTA can cause morphological damages after four hours.

Capillary collection

If you use capillary tubes, we recommend you to use plain micro hematocrit tubes of approximately a 1 mm internal diameter.

If these tubes are filled at least halfway, they easily deliver a drop of blood.

Sticks collection

If you use sticks, it is more difficult to control the quantity of blood.

We recommend that you touch only one of the sticks to the slide to deliver the desired quantity of blood.

If both sticks are touched at the same time, too much blood can be delivered.

1.2. Special Smears

Finger sticks

We do not recommend you to directly apply blood on the slides using fingers.

Using fingers increases the difficulty to manage the quantity of blood and correctly place the drop on the slide.

We recommend you to use a 1 mm capillary tube to transfer the blood.

Make sure that the tube is filled at least halfway so that the blood can easily move.

Reticulocyte smears

We recommend you to keep the initial calibration settings and use a drop of blood half of the normal quantity.

The system produces a slide with a monolayer over the major area.

You must clean the spreader blades after each specimen.

Lupus Erythematosus Preparation

We recommend you to deliver a small quantity of the prepared buffy-coat material on the target and to set the smear control button at its slowest settings.

You must clean the spreader blades after each specimen.

Related information:
- To Calibrate the System, p.22
- To Clean the Spreader Blades, p.25

2. Adjusting the System before Operation

2.1. To Install the System

The HEMAPREP system is shipped with glass blades assembled.

1. Place the system in horizontal position or on a level surface.
   The system must not be placed near a vibrating device.
2. Make sure that the slides have the following characteristics:
   - Correctly cut (not too long or too short)
   - Square ends
   - Frosted area not too large
3. If one of the slides has a listed defect, discard it.
4. Make sure that the slides are cleaned.
5. Place the provided slides in the slots and make sure that they are correctly blocked.
   - If you use frosted slides, place the frosted end at the front of the tray.
   - If you need a single smear, place a factitious slide in the second tray.

Related information:
- To Clean the Spreader Blades, p.25

2.2. To Calibrate the System

This procedure tells you how to adjust the smear length using the smear control button located at the top of the system.

Note that the smear control button is factory adjusted to provide a medium-long smear.

You may have to perform this adjustment in case of samples with extremely high or extremely low hematocrit levels.

1. Move the spreader arm sightly forwards and hold.
   The smear control button adjusts the rate of air escapement from the piston and thus controls the return rate of the spreader holder arm.
2. Slightly rotate the smear control button according to the required result:
   - Rotate the button in 1/8 of a turn clockwise to slow the spreader arm return and produce a longer and thinner smear.
   - Rotate the button in 1/8 of a turn anti-clockwise to speed up the spreader arm return and produce a thicker smear.

2.3. To Determine the Pause Control Time

The pause control determines the time that the spreader blades stay in contact with the blood drop.

The pause control screw is located below the system and is factory adjusted.

Never completely tighten the screw during the adjustment.

Never force the lever during the adjustment.

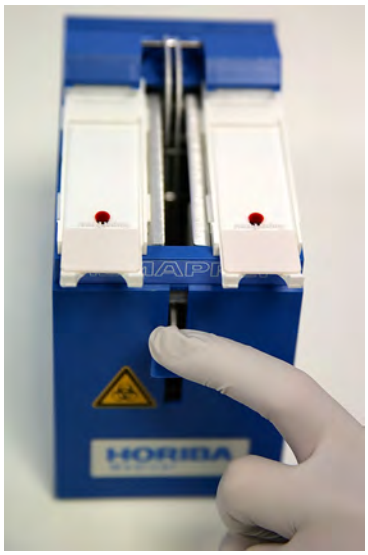
1. Check the pause control time. To do so:
   a. Push the front lever down and immediately release it.
      The lever remains pushed down one second and then begins to rise.
   b. Measure the time the lever remains fully pushed down.
2. Adjust the pause control time:
   - Rotate the screw in 1/8 of a turn clockwise to increase the pause control time.
   - Rotate the screw in 1/8 of a turn anti-clockwise to decrease the pause control time.
3. Check the pause control time to make sure the adjustment is correct.

3. Performing the Test

3.1. To Spread the Samples

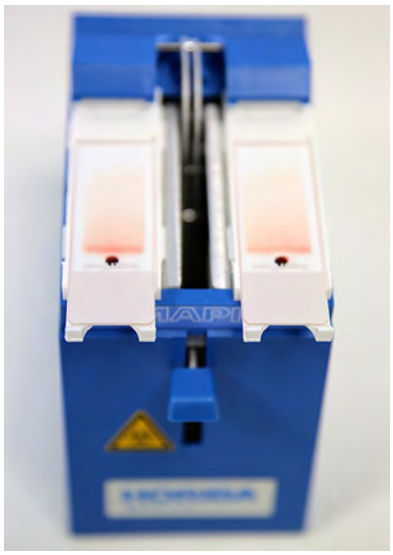
You must have cleaned and placed the slides on the system.

1. Locate the target locations indicated by marks on the trays.
2. Deliver a drop of blood on the indicated marks on the slides, with approximately the same diameter.
3. Gently but firmly depress the lever in the front of the system.



The spreader blades get in touch with the drop of blood.

4. Release the lever as soon as it is fully depressed.
The lever moves back to its original position according to the speed defined by the air piston screw. The desirable speed is one second.
The spreader blades moves back to their home position, spreading the samples and producing the required smear defined during the calibration. The speed is defined according to the smear control button adjustment.



5. Remove the slides and check the spread quality.
6. Clean the spreader blades using a tissue dampened with a disinfectant product.

3.2. To Clean the Spreader Blades

Never immerse the system.

1. Rotate the spreader arm backwards to reach its rest position.
2. Clean the spreader blade using a tissue dampened with a disinfectant product.
3. Wait a few seconds for the spreader blade to dry.
4. If you inadvertently spilled blood into mechanism, immediately use a mild soap solution to clean the parts.

Maintenance and Troubleshooting

1. Cleaning Procedure

1.1. Cleaning Frequency

The laboratory has to determine the spreader blades cleaning frequency.

A small number of cells remain on the spreader blades.

Experiments run by the original manufacturer show that approximately five to ten leukocytes have carried over from one smear to the next, where they typically are mixed with approximately 20000 leukocytes.

We recommend you to clean spreader blades:

- After each test
- When the system did not operate for several hours, to remove dust and foreign particles

1.2. To Clean the Spreader Blades

Never immerse the system.

1. Rotate the spreader arm backwards to reach its rest position.
2. Clean the spreader blade using a tissue dampened with a disinfectant product.
3. Wait a few seconds for the spreader blade to dry.
4. If you inadvertently spilled blood into mechanism, immediately use a mild soap solution to clean the parts.

2. Replacement Procedures

2.1. Consumables

Here is the list of consumables you may need on your system:

Designation	Reference
SPREADER BLADES	1300029910
SPREADER HOLDER REPAIR KIT	1300029912
SLIDE TRAYS DOMESTICS	1300029913
SLIDE TRAYS INTERNATIONAL	1300029914

HEMAPREP is made of rugged material and does not require periodic adjustment or lubrication.

For more detailed information, please contact your local HORIBA Medical representative.

2.2. To Replace the Spreader Blades

You need the following elements to perform this procedure:

- *1300029910*

The spreader blades used in the system are manufactured of high-strength glass and designed for long term operation (several months).

Replace the spreader blades if nicked or cracked because it may cause streaks in the smears.

1. Hold the spreader assembly and remove the spreader blade using the thumb and forefinger.
2. Remove the protective paper of the new spreader blade provided with the system.
3. Insert the new spreader blade in the spreader assembly and firmly press.

Check the spread quality after spreader blades replacement.

2.3. To Replace the Spreader Holders

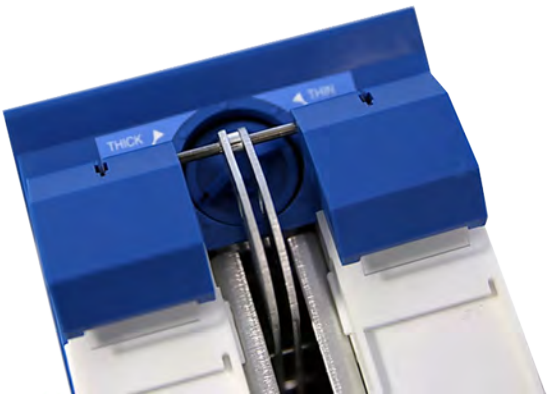
You need the following elements to perform this procedure:

- *1300029912*

The spreader holder kit consists of the following elements:

- One pair of spreader blades
- Two spreader holders with attached weights
- Four "E" rings (two are extras)

1. Remove the two "E" rings holding the spreader holders.
   These rings are probably sprung and not reusable.
2. Remove the spreader blades.
3. Place the new spreader holders so that the two "E" rings snap into the groove on the pivot pin.
4. Insert the spreader blades back:
   a. Make sure that the previously removed spreader blades are intact. If not, replace with new ones.
   b. If necessary, replace the double-sided tape that holds the blades.
   c. Place the spreader blades back to their initial positions.
   d. Clean the spreader blades.



Check the spread quality after spreader holders replacement.

3. Troubleshooting Procedures

3.1. Non Homogeneous Smears

The smears appear:

- erratic with a rough edge
- with streaks
- with a dip in the center of the feathered edge

Cause	Solution
Blood is trapped in the front of the spreader blade.	Do not hold the lever down too long. Release it as soon as it reaches its bottom position. Avoid pressing down the lever too rapidly. Avoid jerking the lever when you remove your finger from it. Avoid delivering the blood drop off the target location. Adjust the pause control time if necessary.
Spreader blades are dirty.	Clean the blades.
Spreader blades are nicked.	Replace the nicked blades.
There are bubbles in the blood drop.	Avoid dispersing the blood drop in such a way that it produces bubbles. If bubbles are produced, attempt to pop them using the edge of the pipette or wooden stick.
Slides are dirty.	Do not use slides that appear to be particularly dirty or greasy.
The blood drop is dried.	Push the lever immediately down after the blood drop has been applied to the slide.

Related information:
- To Clean the Spreader Blades, p.25
- To Replace the Spreader Blades, p.29
- To Determine the Pause Control Time, p.23

3.2. Excessively Long Smears

Cause	Solution
The blood drop is too large.	Apply a smaller blood drop.
The smear is too thin or the blood has very low hematocrit level.	Rotate the smear control button in 1/8 of a turn anti-clockwise until a satisfactory setting is obtained.

Related information:
- To Calibrate the System, p.22

3.3. Excessively Short Smears

Cause	Solution
The blood drop is too small.	Apply a larger blood drop.
The smear is too thick or the blood has high hematocrit.	Rotate the smear control button in 1/8 of a turn clockwise until a satisfactory setting is obtained.

Related information:
- To Calibrate the System, p.22

3.4. Short Smears and Bullet-Shaped Feather Edge

Cause	Solution
The blood drop is too small.	Apply a slightly larger blood drop.
The blood is too thick.	Use two drops of blood. Place a drop on either side of the target area.

3.5. Bullet-shaped Smears

Cause	Solution
Spreader blades did not stayed long enough in the blood drop.	The pause control time is too short. Adjust the pause control time. Fully push the lever to its bottom position.

Related information:
- To Determine the Pause Control Time, p.23

3.6. Lopsided Smears

Cause	Solution
Blood drop is not placed in the center of the target area.	Deliver the blood drop on the target area.
Spreader blade is not positioned firmly in its slot.	Make sure that the spreader blade is centered in its slot. Re-position the spreader blade.

3.7. Incomplete Pickup of Blood Drop

Cause	Solution
Spreader blade is not in contact with blood drop. The drop was delivered behind the target area.	Deliver the drop of blood directly on the target location. If insufficient blood is still picked up, deliver the drop slightly before the target location (in direction of the spreader blade).

3.8. Drop of Blood Does not Spread Out

The drop of blood does not spread out when delivered and moisten the slide.

Cause	Solution
Slide is dirty.	Replace the slide.
Blood dispenser is held at an angle which is too vertical.	Hold dispenser at about a 45° angle when the blood drop is dispensed. The amount of blood which is delivered can be controlled by the angle at which the dispenser is held.

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