Swelab Alfa Plus

Intended Use

The Boule Cleaning Kit is intended for use with the Swelab Alfa Plus Hematology Systems. The kit contains 3 different cleaning solutions as indicated on their labels. Using this cleaning kit at the stated regular intervals will ensure:

- Longer lifetime of instrument tubing
- Lower risk of bacterial grow
- Lower background counts
- Increased mean time between failure (higher MTBF)

Contents

- 1. Enzymatic Cleaner, 450 mL, blue-colored solution
- 2. Hypochlorite Cleaner; 450 mL, yellow-colored solution
- 3. Detergent Cleaner, 450 mL, red-colored solution

The contents can be used for three full and complete cleaning cycles. Remaining cleaning solution should be disposed of.

Storage and stability

The Boule Cleaning kit can be transported at ambient temperature (avoid freezing, allow adaption to room temperature before use). Always store the bottles in an upright position to avoid any leakage from the cap.

Cleaning Interval

It is recommended to use the cleaning kit at the following time intervals:

| Less than 50 samples/day | \rightarrow | every 6 months |
|--------------------------|---------------|----------------|
| More than 50 samples/day | \rightarrow | every 3 months |
| 100-200 samples/day | \rightarrow | every month |

Procedure

It is very important that the cleaning procedure is performed in the correct order *(or it may result in high PLT background counts)*. The following order must be followed:

- 1) Enzymatic Cleaner (enzyme solution blue cap)
- 2) Hypochlorite (2% solution white cap)
- 3) Detergent Cleaner (detergent solution red cap)

Proceed as follows:

- 1. Firstly, remove the diluent and lyse level sensors from their containers.
- 2. Press [Main menu] on the touch screen, then [Maintenance], and then the arrow [>] to enter the Cleaning Menu.
- 3. Press [Clean Empty] and wait for the system to empty.
- 4. Wet a soft tissue with the proper cleaning solution (*e.g. the first time use Enzymatic Cleaner*) and wipe both level sensors clean on the outside. Then insert both level sensors directly into the cleaning solution bottle.
- From Cleaning Menu press [Clean Fill]. Allow the system to fill up with the cleaning solution and wait 15-30 minutes for the cleaner to work.
- 6. Remove both level sensors and press [Clean Empty]. Allow the system to empty completely.
- 7. Repeat step 4 to 6 using the Hypochlorite (white) followed by the Detergent Cleaner (red).



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- 8. Finally take a soft tissue and wet it with Diluent (**not** Lyse) and wipe off any remaining cleaner from the level sensors. Make sure that a soft and dry tissue is used to dry the level sensors from all remaining liquid. When level sensors are clean insert both back into the original reagent containers. (Be sure not to interchange the Diluent and Lyse level sensors.)
- 9. From Cleaning Menu press [Clean Fill], wait until this cycle is completed.
- 10. The background count should not exceed the recommended values, which is stated in the User manual. Perform a minimum of 3 background counts before analyzing the next sample.

Notes

- As the volume in the cleaning bottles will decrease during the cleaning cycles, be sure to secure the bottles to avoid tilting.
- During the described cleaning process above, some foaming might occur on the aspiration needle. Remove foam with a soft tissue.
- In case of heavy contaminated systems, it is recommended to warm the detergent to 45-55 °C prior to cleaning the system.
- Only the Hypochlorite Cleaner has the ability to act as a disinfectant, significantly reducing the number of viable microorganisms.
- It is recommended to check calibration by running a control after cleaning.

Precautions

- Boule Hypochlorite Cleaner (2%) contains sodium hypochlorite (2%). The solution is skin irritating and causes serious eye irritation. It is marked with a hazard pictogram. The other two solutions do not contain chemicals at a level considered to be hazardous to health. However, all solutions should be handled with proper care, and skin and eyes should be protected. Please read the SDS before use. Since hypochlorite solutions are oxidizing with a basic pH, avoid contact with materials other than those indicated in the instructions (spills give a remaining smell on e.g. skin and stains (bleaching) on clothes etc).
- The concentration of hypochlorite decreases with time without invalidation of the functionality within the given expiry. Close the container as soon as possible after use.
- Cleaners should only be used before stated expiration date. The cleaners should be disposed of according to local regulations. When draining through the sewage system, always use plenty of water.

ORDERING INFORMATION AND SERVICE

Contact your local distributor for orders and support. Please have the product number ready for orders. For other assistance contact Boule Medical AB at phone +46 8 7447700, fax +46 8 7447720 or info@boule.com

For translation of this instruction and explanation to symbols see <u>www.swelab.com</u> support/downloads.

| Ordering no: | Description | Packaging |
|--------------|--------------------|------------|
| 1504111 | Boule Cleaning Kit | 3 x 450 mL |