

Instructions for use

Boule Cleaners



Revision history

Latest revision: 2024-02. Previous revision: 2023-10.

Changes: Document updated for clarity and conformity, all information either added or updated.

Boule Cleaners

Boule Cleaning Kit contains:

- Boule Enzymatic Cleaner, 450 mL, blue-colored solution
- Boule Hypochlorite (2%) Cleaner, 450 mL, yellow-colored solution
- Boule Detergent Cleaner, 450 mL, red-colored solution

Boule Enzymatic Cleaner and Boule Hypochlorite (2%) Cleaner are also available as separate products, Boule Enzymatic Cleaner 100mL, and Boule Hypochlorite (2%) Cleaner 500 mL.

Intended purpose and user requirements

- Boule Cleaning Kit, Boule Enzymatic Cleaner, and Boule Hypochlorite (2%) Cleaner are accessories intended for cleaning and maintenance of Medonic M-series and Swelab Alfa-series hematology analyzers in a professional laboratory setting. The products have no direct function on the analytical / clinical performance of the hematology analyzers.
- The cleaners are intended for professional use. Operator must have basic laboratory skills, be aware of good laboratory practice, and read the user manual before use.

Number of uses

- Boule Cleaning Kit (3 × 450 mL): 3 full and complete cleaning cycles.
- Boule Enzymatic Cleaner (100 mL): Up to 20 clot prevention procedures, depending on analyzer model.
- Boule Hypochlorite (2%) Cleaner (500 mL): Up to 50 cleanings of the pre-dilute inlet.

Principle of operation

- Boule Enzymatic Cleaner: A proteolytic enzyme breaks down proteins, causing debris on surfaces to loosen or be removed.

- Boule Hypochlorite (2%) Cleaner: Hypochlorite oxidizes organic molecules, thereby cleaving the molecules and/or lessening their surface adherence.
- Boule Detergent Cleaner: Sodium dodecyl sulfate facilitates debris removal by binding to charged groups and increasing solubility.

Transport, storage, and stability

- The cleaners can be transported at ambient temperature (avoid freezing, allow adaptation to room temperature before use).
- Always store the bottles in an upright position to avoid any leakage from the caps.
- The cleaners are stable at least up to the expiration date as shown on the label when stored at a temperature between 4°C to 30°C. Discard opened containers after 3 cleaning cycles (stable up to 6 months after opening).
- Operating temperature is between 18°C to 30°C.
- The concentration of hypochlorite decreases with time without invalidation of the functionality within the given expiry time. Close the container as soon as possible after use.
- Prolonged storage above 30°C may result in lessened cleaning activity due to auto-degradation of the enzyme and lessened cleaning activity and disinfecting activity due to auto-degradation of the hypochlorite.

Precautions

- Please read the relevant Safety Data Sheet (SDS) before use. SDSs are available at www.boule.com.
- Boule Hypochlorite (2%) Cleaner is classified as hazardous to health according to the CLP [Regulation (EC) no 1272/2008]. The required labeling is given below. See the SDS for detailed information.

Hazard Pictogram:



Signal Word:

Warning

Hazard statements:

H315 causes skin irritation.
H319 Causes serious eye irritation. **H412** Harmful to aquatic life with long lasting effects.

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Precautionary statements:

P273 Avoid release to the environment. **P280** Wear protective gloves and eye protection. **P305+P351+P338** IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. **P337+P313** If eye irritation persists: Get medical advice/attention. **P501** Dispose of contents and container to authorized waste disposal facility.

- Boule Detergent Cleaner and Boule Enzymatic Cleaner are not considered hazardous to health. See SDS for detailed information. Required labeling: **EUH210** Safety data sheet available on request. **EUH208** Contains REACTION MASS OF 5-CHLORO-2-METHYL-2H-ISOTHIAZOL-3-ONE AND 2-METHYL-2HISOTHIAZOL-3-ONE (3:1). May produce an allergic reaction.
- Handle all the cleaning solutions with proper care. Protect skin and eyes.
- 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 stain (bleaching) on clothes etc.).
- Do not use the cleaners after the expiration date.
- The cleaners are intended for use as supplied. Adulteration by dilution or addition of any materials to the products invalidates any use of them on an in vitro diagnostic (IVD) device.
- Dispose of cleaners according to local regulations. When flushing left-over cleaner down the drain, always use plenty of water. The bottle can be recycled after rinsing.

Serious incident

If a serious incident occurs in relation with Boule Medical's product, a notice shall be reported to the distributor, the manufacturer Boule and the competent authority of the Member State in which the user and/or the patient is established.

Benefits of regular cleaning

Cleaning the analyzer at the stated regular intervals will ensure the following:

- longer lifetime of instrument tubing
- lower risk of bacterial growth
- lower background counts
- increased mean time between failure (higher MTBF)

Cleaning intervals

Recommended cleaning intervals:

- Clean the pre-dilute inlet with Boule Hypochlorite (2%) Cleaner: *every month*.
- Perform Clot Prevention with Boule Enzymatic Cleaner: *every month or every 1000 samples*.
- Clean with Boule Cleaning Kit:

Less than 50 samples per day	→ <i>every 6 month</i>
More than 50 but less than 100 samples per day	→ <i>every 3 month</i>
100-200 samples per day	→ <i>every month</i>

Clot prevention with Boule Enzymatic Cleaner

Perform the following cleaning procedure using Boule Enzymatic Cleaner at least every month or every 1000 samples. It takes approximately 15 minutes.



- Once this procedure is started, the operator will be unable to abort the cycle until it is completed.
- If the cycle is aborted prematurely, the system should be cleaned properly to avoid erroneous patient results.

1. Clean the aspiration probes using a paper tissue with a 70% alcohol solution.
2. Fill a beaker with 5 mL of Boule Enzymatic Cleaner.
3. If the system has the optional Cap Piercer or Auto Sampler, fill a CLEAN standard 4.0–5.0 mL tube to half with Boule Enzymatic Cleaner.
4. From **Main Menu**, press **Maintenance** and then press **Clot Prevention**.
5. If the system has a Cap Piercer: open door to Cap Piercer, insert the tube containing cleaner upside down, press the tube in place, close the door, and go to Step 7.
6. If the system has an Auto Sampler: Place the tube containing cleaner in Position 1 on the wheel and lock wheel into place.

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7. Hold the beaker containing cleaner under the OT probe and submerge probe in cleaner.
8. Press **OK** to confirm. To allow aspiration to complete for all inlets, wait at least 5 seconds after aspiration has stopped before removing the beaker.
9. The system will perform the cleaning process for all analysis modes simultaneously.
10. When the cleaning process has completed, perform at least one background count for each inlet, see section [Background count \[3\]](#). If all values are acceptable, the analyzer is ready for the next analysis.

Clean the pre-dilute inlet with Boule Hypochlorite (2%) Cleaner

Perform the following cleaning procedure using Boule Boule Hypochlorite (2%) Cleaner every month. It takes approximately 10 minutes.

1. Clean the aspiration probes using a paper tissue with a 70% alcohol solution.
2. Fill a beaker with 10 mL Boule Hypochlorite (2%) Cleaner.
3. Fill another beaker with 18 mL diluent, preferably by using the dispense function:
 - a. In the **Start Menu** press **Dispense**.
 - b. Place a beaker for waste under the pre-dilute aspiration probe (the probe in front of the predilute start plate).
 - c. Press the pre-dilute start plate. The instrument will dispense a small amount of diluent. Discard this.
 - d. Place a clean beaker under the pre-dilute aspiration probe and dispense 18 mL into the beaker by pressing the start plate again.
 - e. Press **Exit**.
4. Aspirate the hypochlorite as a pre-dilute sample.
5. Aspirate diluent as a pre-dilute sample. Repeat.
6. Perform at least one background count in the predilute mode, see section "**Background Count**". If all values are acceptable, the analyzer is ready for the next analysis.

Clean with Boule Cleaning Kit

Boule Cleaning Kit contains 3 solutions. Use the solutions in the following order, failing to follow this order might result in high PLT background counts.

1. Boule Enzymatic Cleaner (enzyme solution - blue cap)

2. Boule Hypochlorite (2%) Cleaner (hypochlorite solution - white cap)
3. Boule Detergent Cleaner (detergent solution - red cap)

Perform the following steps:

1. Remove the Diluent and Lyse level sensors from their containers.
2. On the display, press **MENU**, then press **ADVANCED**, then **MAINTENANCE**, and then **CLEANING MENU**.
3. Press **CLEAN CYCLE EMPTY** and wait for the system to empty.
4. Wet a soft tissue with the proper cleaning solution (e.g., the first time use Boule Enzymatic Cleaner) and wipe both level sensors clean on the outside.
5. Insert both level sensors directly into the cleaning solution bottle.
6. From **Cleaning Menu**, press **CLEAN CYCLE FILL**. The system will fill with cleaning solution. Leave the cleaner in the system for 15–30 minutes. Remove both level sensors and press **CLEAN CYCLE EMPTY**. Allow the system to empty completely.
7. Repeat Step 4 to Step 7 using Boule Hypochlorite (2%) Cleaner (white cap), then repeat Step 4 to Step 7 using Boule Detergent Cleaner (red cap).
8. Take a soft and dry tissue and wet it with diluent (**not** lyse) and wipe off any remaining cleaner from the level sensors.
9. Use a soft and dry tissue to dry the level sensors from all remaining liquid.
10. Insert each level sensor in the correct reagent container. Make sure to put the Lyse level sensor in the Lyse container and the Diluent level sensor in the Diluent container.
11. From the **Cleaning Menu**, press **CLEAN CYCLE FILL** and wait until the cycle is completed.
12. Perform a minimum of 3 background counts. If all values are acceptable, the analyzer is ready for the next analysis.

Background count

For the Pre-Dilute inlet, use diluent as sample. For all other inlets (Open Tube, Autoloader, Cap Piercer or Micro Pipette Adapter), use air as sample.

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For the Cap Piercer, a dark empty tube must be used for the analysis to start. The tube can, for example, be covered by black tape.

Acceptable background count values

Parameter	Accepted values
RBC	$\leq 0.02 (\times 10^{12}/L)$
WBC (*)	$\leq 0.1 (\times 10^9/L)$
HGB	$\leq 0.2 (g/dL)$
PLT	$\leq 10 (\times 10^9/L)$

(*) The Micropipette inlet is acceptable at $\leq 0.2 (\times 10^9/L)$ on WBC due to potential pre-analytical contributions.

Check background count for Autoloader Inlet

1. Load sampling wheel with an empty tube in position 1 if wheel 1 (position 21 if wheel 2).
2. Press **Auto Sampler**, choose wheel number, and mark the desired position sequence field.
3. Choose Background then press **Accept** to save.
4. Press ► button on the left. Aspiration will start. As the analyzer will not detect any blood, the cycle will continue after approximately 10 seconds.
5. Check the analysis results. The background count should not be higher than the values in [Background count \[3\]](#).
6. If values are not acceptable, repeat Step 1 to Step 5. If still not acceptable, investigate and remedy the cause.

Check background count for Pre-Dilute, Cap Piercer, OT, or MPA inlet

1. If checking the background of the Pre-Dilute inlet, dispense diluent in a beaker of at least 10 mL:
 - a. In the **Start Menu**, press **Dispense**.
 - b. Place a beaker for waste under the pre-dilute aspiration probe (the probe in front of the predilute start plate).
 - c. Press the pre-dilute start plate. The instrument will dispense a small amount of diluent. Discard this.
 - d. Place a clean beaker under the pre-dilute aspiration probe and dispense 4.5 mL into the beaker by pressing the start plate again.
 - e. Press **Exit**.

2. From **Start Menu** select the **Background** tab (upper right-hand corner).
3. Start aspiration:
 - If checking the Pre-Dilute inlet: Place the beaker with diluent so the tip of the pre-dilute probe is covered by the solution. Press and hold the predilute start plate until aspiration starts.
 - If checking the Cap Piercer inlet: Insert a dark empty tube upside down, press tube in place and close the door to the Cap Piercer.
 - If checking the Open Tube inlet: Press the whole blood start plate located behind the whole blood sample probe. Aspiration will start. As the analyzer will not detect any blood, the cycle will continue after approximately 10 seconds.
 - If checking the Micro Pipette Adapter inlet: Insert the MPA device without a micropipette into the analyzer.
4. Check the analysis results. The background count should not be higher than the values in [Background count \[3\]](#).
5. If values are not acceptable, repeat Step 1 to Step 4. If still not acceptable, investigate and remedy the cause.

Meaning of symbols on product labels

Article number	Content	Lot number
Manufacturer	Use-by date	Importer
Swiss authorized representative	In vitro diagnostic medical device	Consult electronic instructions for use available on website

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Warning



Caution



Temperature
limitation

IVD

CE

CE

CE marking of
conformity

Ordering information and service

Contact your local Boule representative for orders and support. Please have the article number ready for orders. For other assistance contact Boule Medical AB at phone +46 8 7447700 or visit www.boule.com.

For a translation of this instruction, visit www.boule.com.

Article number	Description	Packaging
1504111	Boule Cleaning Kit	3 × 450 mL
1504112	Boule Enzymatic Cleaner	100 mL
1504113	Boule Hypochlorite (2%) Cleaner	500 mL

Contact information



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CH REP

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Regulatory information

Boule cleaners are considered Class A IVD devices according to the In Vitro Diagnostic Regulation (IVDR) (EU) 2017/746.