

Instructions for use

Boule Cal



Revision history

Latest revision: October 2023. Previous revision: June 2022

Changes: Added Swiss authorized representative. Document updated for IVDR and for clarity and conformity, all information either added or updated.

Intended purpose and user requirements

- Boule Cal is intended for *in vitro* diagnostic use for calibration of red blood cells (RBC); hemoglobin (HGB); mean cell volume of red cells (MCV); white blood cells (WBC); platelets (PLT) on Medonic M-series and Swelab Alfa hematology analyzer.
- The calibrators are intended for professional use. Operator must have basic laboratory skills, be aware of good laboratory practice, and read the user manual before use.

Summary and principles

Multi-parameter hematology analyzers require regular calibration in order to produce accurate results on patient samples. Calibration can be accomplished by transferring information to the analyzer through fresh blood samples, which have been assayed by reference methods. A more direct and convenient approach is to use a calibrator material with System Specific Values (SSV) assigned such as Boule Cal.

Boule Cal is a stable suspension of red blood cells, white blood cells and platelets. Assigned values are derived from replicate analyses on whole blood calibrated hematology analyzers (see reference procedures). A user analyzes Boule Cal on their instrument and computes calibration factors by comparing recovered values and assigned values. These factors provide the basis for making adjustments to the instrument.

Reagents

Boule Cal contains treated, stabilized human erythrocytes and a stabilized platelet-sized component in an isotonic, bacteriostatic medium. Fixed erythrocytes are added to simulate leukocytes.

Storage and stability

Boule Cal is shipped in a thermally insulated container designed to keep it cool. Sealed vials stored in an upright position at 2°C to 10°C, are stable at least up to the expiration date as shown on the product label. Open vial stability is 5 days after opening when returned to refrigerator after each use.

Indication of instability or deterioration

Inability to obtain expected values might indicate product deterioration. Discoloration of the product might be caused by overheating or freezing during shipping or storage. Darkly colored supernatant might be indicative of product deterioration, however, moderately colored supernatant is normal and should not be confused with product deterioration. If the recovered values are not within the expected ranges:

1. Review Instructions for use for the calibrator product and the operating procedure of the instrument.
2. Check the expiration date of the Boule Cal. Discard outdated products.
3. Test an additional unopened vial of Boule Cal.

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Prerequisite: Remove the Boule Cal sample tube from refrigeration and allow to warm at ambient temperature (18°C to 32°C) for 30 minutes before mixing.

Do not use a mechanical mixer to mix Boule Cal.

Do the following:

1. Mix the sample by hand:
 - a. Hold the sample tube in an upright position between the palms of your hands and roll the tube slowly 8 times.
 - b. Invert the tube and slowly roll it between the palms of your hands 8 times.
 - c. Continue to mix in this manner until all cells are completely suspended. Tubes stored for a long time might require extra mixing.
 - d. Gently invert the tube 8 times immediately before sampling.
2. For the calibration procedure, refer to the user manual for your analyzer.

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3. After open sampling, carefully wipe the rim of the tube and inside of the cap with a lint-free tissue. Replace the cap ensuring it is on tight.
4. Return the tubes to the refrigerator within 30 minutes of use.

For further assistance, please contact your local distributor.

Precautions



RISK OF INFECTION

As there are no assurances of the absence of HIV, Hepatitis B or C viruses or other infectious agents in blood samples, controls, and calibrators these products should be handled as potentially biohazardous. Refer to local regulations and established laboratory protocol for handling biohazardous materials.



CAUTION

Never use an opened vial longer than recommended by the manufacturer, past the expiration date, or subject any vial to excessive heat or agitation.

- For *in vitro* diagnostic use.
- Please read the relevant Safety Data Sheet (SDS) before use. SDSs are available at www.boule.com.
- This product should not be disposed in general waste but should be disposed with infectious medical waste. Disposal by incineration is recommended.
- This product is intended for use as supplied. Adulteration by dilution or addition of any materials to the product as supplied invalidates any diagnostic use of the product.

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.

Hazard information

Any hazard related to the content of a consumable is indicated by a hazard code on the product label. See table below. For more information refer to the relevant Safety Data Sheet (SDS) at www.boule.com.

Hazard Code	Explanation
EUH 208	Contains a reaction mass of 5-CHLORO-2-METHYL-2H-ISOTHIAZOL-3-ON and 2-METHYL-2H-ISOTHIAZOL-3-ON. May produce an allergic reaction.
EUH 210	Safety Data Sheet available on request.

Reference procedures

WBC

A series of 1:500 dilutions are made using class A glassware. The lytic reagent is placed in the initial dilution flask before diluting to volume. The diluting agent is an isotonic solution for Beckman Coulter® instruments. The samples are counted on a Beckman Coulter Counter Z instrument.

RBC

A series of 1:50,000 dilutions are made using class A glassware. The diluting agent is an isotonic solution for Beckman Coulter® series instruments. The samples are counted on a Beckman Coulter Counter Z instrument.

Hgb

Hemoglobin concentration is determined by converting hemoglobin to hemoglobincyanide (HiCN) and measuring absorbance at 540 nm according to CLSI H15-A3 and ICSH recommendations. Hemoglobin concentration is calculated using millimolar absorption coefficient of 11.0.

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HCT

Microhematocrit values are done in replicate on each sample, with capillary tubes filled and centrifuged according to the CLSI H7-A3 document. K3EDTA is used as the anticoagulant for collection of fresh specimens. The packed cell volume, or hematocrit, is read directly using a precision metric scale. No correction is made for trapped plasma.

Plt

A series of 1:125 macrodilutions are prepared using class A glassware in 1% Ammonium Oxalate. Charged hemacytometers are allowed to stand 20–30 minutes. Cells are counted using phase-contrast microscopy technique.

MPV

Based on a method using latex particles.



Biohazard



Caution



Temperature limitation



CE marking of conformity



Calibrator

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.

Meaning of symbols on product labels



Article number



Content



Lot number



Manufacturer



Use-by date



Importer



Swiss authorized representative



In vitro diagnostic medical device



www.boule.com

Consult electronic instructions for use available on website

Article number	Description	Packaging
1504025	Boule Cal	1 x 3.0 ml
1504045	Boule Cal	2 x 3.0 ml
1504022	Boule Con-Diff Tri-Level, 16 parameter	6 x 4.5 ml
1504020	Boule Con-Diff Low, 16 parameter	1 x 4.5 ml
1504176	Boule Con-Diff Low, 16 parameter	6 x 4.5 ml
1504019	Boule Con-Diff Normal, 16 parameter	1 x 4.5 ml
1504043	Boule Con-Diff Normal, 16 parameter	6 x 4.5 ml
1504021	Boule Con-Diff High, 16 parameter	1 x 4.5 ml

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Article number	Description	Packaging
1504216	Boule Con-Diff High, 16 parameter	6 x 4.5 ml

Contact information



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E-mail:info@boule.com
Web:www.boule.com



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Regulatory information

Boule calibrators are considered general IVD devices under the In Vitro Diagnostic Directive 98/79/EC.

