

Exigo™ H400 veterinary hematology system

Committed to animal health, veterinarians look for solutions that offer the best possible care. For diagnostic testing, this includes accurate results, instrument reliability, and species optimization but also meeting the needs of the very special patients that are our family members.

Designed for robustness and ease-of-use, the Exigo hematology system suits many types of veterinary clinics:

- Twelve pre-installed animal profiles provide flexibility
- MPA technology enables a complete blood count from one drop of blood in one minute
- Robust equipment design helps ensure instrument uptime

System overview

Exigo H400 is an automated veterinary hematology analyzer tailored to various-sized laboratories and veterinary hospitals (Fig 1). The analyzer features a high-precision shear valve for accurate sample aspiration and dilution. A closed shear valve design minimizes leakage risk, ultimately reducing the maintenance requirements.

Exigo H400 employs well-proven and robust measurement technologies. The analyzer uses impedance for white blood cell (WBC), red blood cell (RBC), and platelet (PLT) counts, while hemoglobin (HGB) is determined spectrophotometrically. The analyzer provides quantitative results for 19 parameters, with histograms for WBC, EOS, RBC, and PLT (Fig 2).

The sample analysis software displays information messages related to pathology that might be present in the sample.

The sample pathology information includes a short message, defining the sample abnormality followed by recommendations for that sample. The information can be triggered by the following mechanisms:

- Histogram shape abnormalities detected by system software calculations.
- Selected values that exceed defined limits outside the reference range.



Fig 1. Exigo H400 system with built-in tube mixer and Micro-pipette adaptor (MPA).

These messages occur when selected values are moderately to markedly abnormal. Values slightly outside the reference interval are typically treated as cautionary by the clinician.

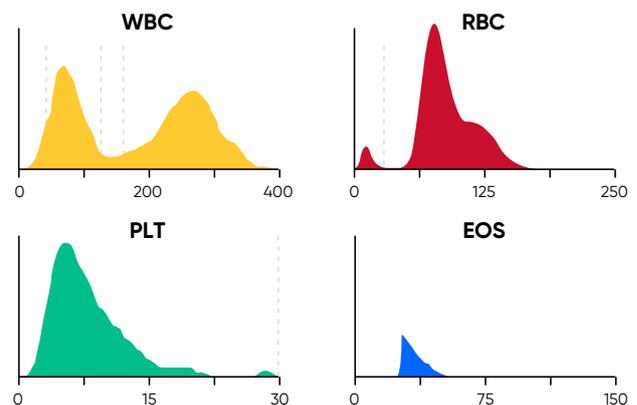


Fig 2. Exigo H400 analysis results visualized in histograms for WBC, RBC, PLT, and EOS.

Key components

Shear valve technology

Every Exigo H400 analyzer comes equipped with a high-precision shear valve that cuts out an absolute sample volume to be used for analysis (Fig 3). The closed design minimizes user maintenance needs, thereby maximizing instrument uptime. The closed design prevents entry of environmental impurities that might cause contamination and leakage. Additionally, the shear valve is automatically flushed with Diluent to prevent build-up of salt deposits that might also cause leakage. To avoid wear and tear of the shearing discs, the shear valve is soaked in Diluent, ultimately mitigating the need for replacement.

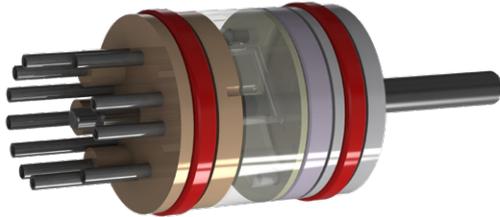


Fig 3. Maintenance-free Exigo H400 valve secures accurate results and lowers maintenance costs.

Atmospheric pressure variations will not affect the blood cell count. High altitude compensation only needs to be activated if various indicators related to HGB measurement problems repeatedly appear (see Section 9 in User manual). At higher elevations, the mode might need to be changed to Moderate or Maximum compensation. For high altitude compensation, the software incorporates some minor timing sequences for the wash cycles, no other functions are affected.

A blood sensor prevents inaccurate results caused by air in the sample. When enabled, aspiration stops when blood is detected by the blood detector sensor. This functionality can be disabled by the operator to instead employ a fixed aspiration type.

Sample aspiration modules

To maximize utilization of the Exigo H400 analyzer, sample aspiration can be performed through two different aspiration modes (Fig 4). The whole blood sample probe aspirates from open tube for analysis. After aspiration, the analyzer will perform an automatic probe flush for cleaning of the sample probe.

Aspiration fails can be caused by, for example, sample shortage, clogging, or air bubbles in sample tube. The built-in maintenance tools ensures that there is no blockage of tubing or leakage that might cause the sample not to be aspirated properly.

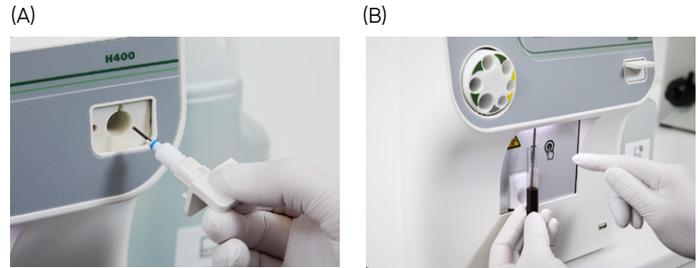


Fig 4. Exigo H400 allows sample aspiration from (A) open tube or (B) micro-pipette adapter.

Micro-pipette adapter (MPA) inlet

The micro-pipette adapter (MPA) enables a complete blood count (CBC) from one drop of blood using a capillary sample tube, a functionality well-suited for small animals and dehydrated patients. Only use Boule-supplied, plastic, high precision EDTA capillary tubes with the MPA inlet. Glass tubes can cause damage to the analyzer if inserted incorrectly.

As the MPA inlet bypasses the shear valve sample aspiration, it is of utmost importance to ensure correct volume is collected by making sure the whole capillary is filled with blood and by wiping of any excess blood outside of the capillary before sliding it into the MPA module (Fig 5).

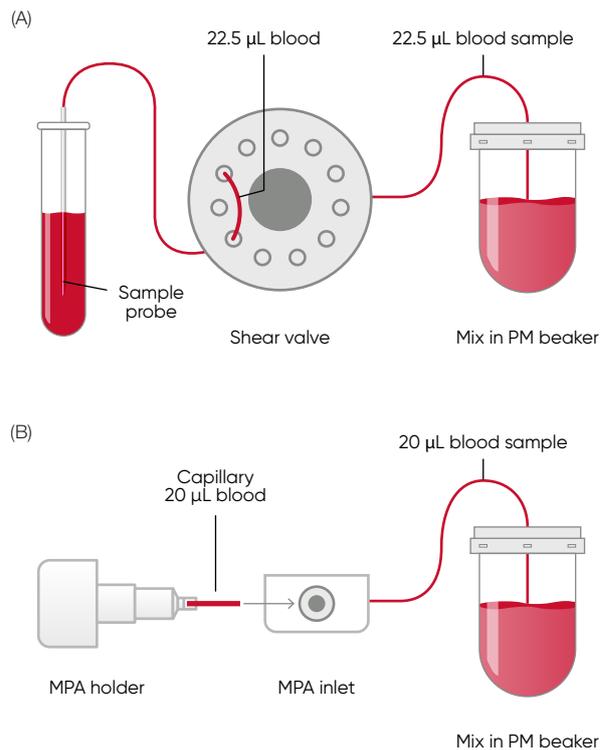


Fig 5. Sampling for (A) open tube inlet, using the shear valve, as well as for (B) the MPA inlet, bypassing the shear valve. The difference in sample volume is compensated for in the instrument software.

Measurement chambers

RBC and PLT counts are conducted in the RBC chamber, using floating discriminators. A typical challenge with animal blood is the small RBCs and PLTs of some animal species that are hard for automated hematology systems to detect. Due to these large variations in the size of RBCs and PLTs (MCV and MPV), Exigo H400 is equipped with a narrower capillary aperture of 60 µm, as compared to that of Boule's human analyzer utilizing a 80 µm aperture. This enables for smaller RBC and PLT cells to be detected in the capillary, with a higher sensitivity.

WBC count is conducted in the WBC chamber. As for RBC and PLT, the WBC differential is performed using floating discriminators to estimate the best separation between the cell populations. The EOS count is also conducted in the WBC chamber, and similar to the WBC, RBC and PLT count, where the eosinophil count is also measured using impedance technique together with fixed discriminators (Fig 6).

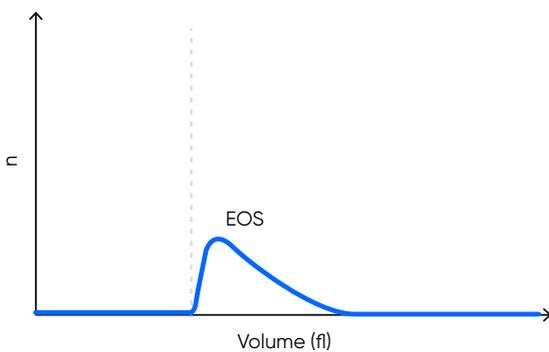


Fig 6. The Exigo H400 system uses a floating discriminator technology to estimate the best separation between three populations of white blood cells (LYM, GRA, and MONO cell fractions) and a fixed discriminator when calculating the EOS cell fraction.

After the WBC count is performed, new sample is obtained from the first aspiration by passing through the shear-valve to get an exact volume (Fig 7). HGB is determined from the same dilution as the WBC (Fig 8). The HGB reading is slightly corrected for turbidity in case of extreme WBC counts. When the analyzer is in standby mode, the LED lamp is switched off to extend its lifetime.

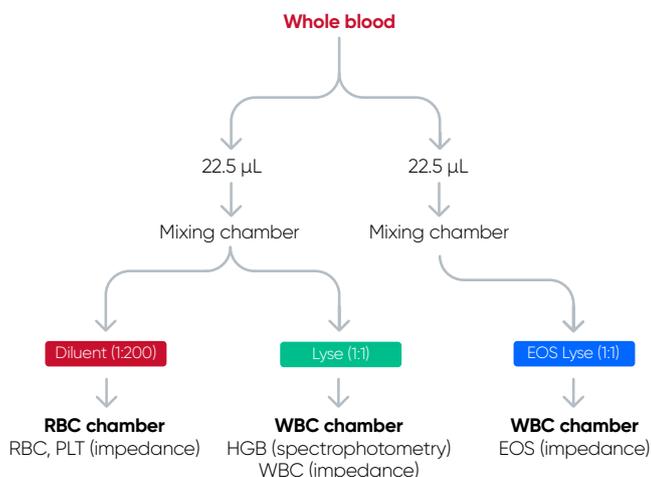


Fig 7. Exigo H400 measurement principle.

$$\text{HGB (g/L)} = \text{Constant} \times \ln \left(\frac{\text{Blank photocurrent}}{\text{Sample photocurrent}} \right)$$

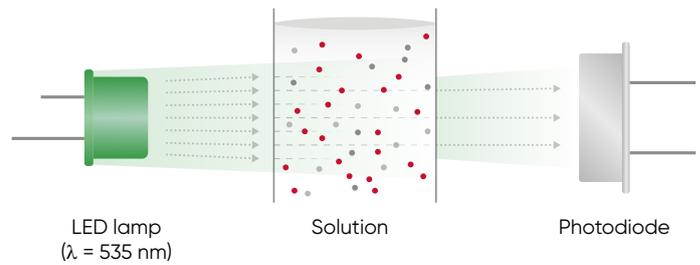


Fig 8. HGB is determined spectrophotometrically, using a LED lamp mounted on one side of the WBC chamber. The light is allowed to pass the flow chamber and transmitted light is detected by an optical sensor mounted on the opposite side. HGB concentration is calculated as a difference of a blank and a blood measure with and without illumination to reduce the effect of liquid refraction and disturbing light.

Liquid system

The fluidic system is controlled by pumps that generate pressure and vacuum. Reagent pipettes, featuring optical sensors, ensure accurate dilution of the sample. No pistons or other moving parts are used in the dilution system to minimize the maintenance and service needs. For the cell count, measuring pipettes equipped with liquid start and stop sensors ensure that a correct volume is used for analysis. The air pump generates a pressure that pushes the finally diluted sample through the aperture in the measuring chambers. To reduce risk for clogging, high voltage burning of the aperture (based on generated air bubbles) is automatically carried out, but only when needed to reduce wear and tear.

The analyzer performs automatic cleaning every 48 hours, using diluent, and an enzymatic cleaning cycle, using the on-board cleaner reagent, to dissolve proteins and prevent clots at each enter-standby cycle. The Boule-designed maintenance free valves automatically relieve upon standby to prevent wearing of the tubing.

It is recommended to keep the analyzer switched on at all times. The instrument will automatically enter standby after a user-settable idle time. In case the analyzer needs to be turned off, for example, for transportation (< 12 h), use the **Power Down** button in the **Maintenance** menu. Power down ensures proper shutdown of the software and preparation of the liquid system prior to power off. When the display goes blank, the analyzer can be securely turned off. For long-term storage (> 12 h), the analyzer should be cleaned and emptied before power down. For more information, please refer to Section 10 "Analyzer care and maintenance" in the user manual.

When put into use after being turned off, use the **Power-up** function to prime the analyzer. Upon selecting **Power-up** or **Exit standby**, the valves will close and the analyzer will be ready for use.

In the event of an error message, verify that the analyzer is filled and run a prime cycle, using built-in maintenance tools. The prime cycle is used to reset the analyzer after an error has been indicated or a failure in running a sample occurs.

Reagents

Depending on the analysis the user wishes to perform, two or three reagents are required for the Exigo H400 analyzer—Diluent and Lyse for a 3-part analysis (LYM, MONO and GRAN counts) or Diluent, Lyse and EOS Lyse for a 4-part analysis (LYM, MONO, NEU and EOS counts) – which greatly facilitates handling and logistics and helps reduce running costs. The reagents for the Exigo H400 are delivered with a reagent tray to make the bench space more organized. Simply scan the RFID card on the reagent container and the analyzer stores key information such as lot number, open and expiry dates, and remaining volume.

Moreover, for the Exigo H400 veterinary system, there is an additional Cleaner reagent, consumed only during enter standby. The main reason for the additional cleaner is the composition of animal blood, and due to this purpose-designed cleaner, the Exigo H400 is extremely robust and allows the user to run body fluids, whilst eliminating all monthly cleaning procedures.

Not only is the blood dilution ratio critical for an accurate count. The reagent composition is also of utmost importance for reliable results. The Diluent should provide an isotonic environment for the RBCs and PLTs, while the Lyse reagent

should be capable of lysing the RBCs to release HGB and shrink the WBCs to allow differentiation of these cells into their subgroups. The EOS Lyse then further lyses all the WBCs except for the more robust membranes of the eosinophil cells, allowing the Exigo H400 to detect and count them separately. Boule's cell count processes have been tested and optimized for decades for robust and reliable analysis results. The use of the reagents designed by Boule Diagnostics for the specific instrument ensures analytical quality and performance of the hematology system.

To avoid reagent shortage and to ensure an exact sample dilution each time, Boule adds a small extra volume to each reagent container. To prevent air from entering the system, the small volume that is left in the container when all cycles are consumed should not be used. To mitigate the contamination risk, the left-over volume should not be mixed with reagent in a newly opened container.

System performance

Exigo H400 provides a robust performance, with analysis results comparable with those from a reference instrument (Fig 9 to 11).

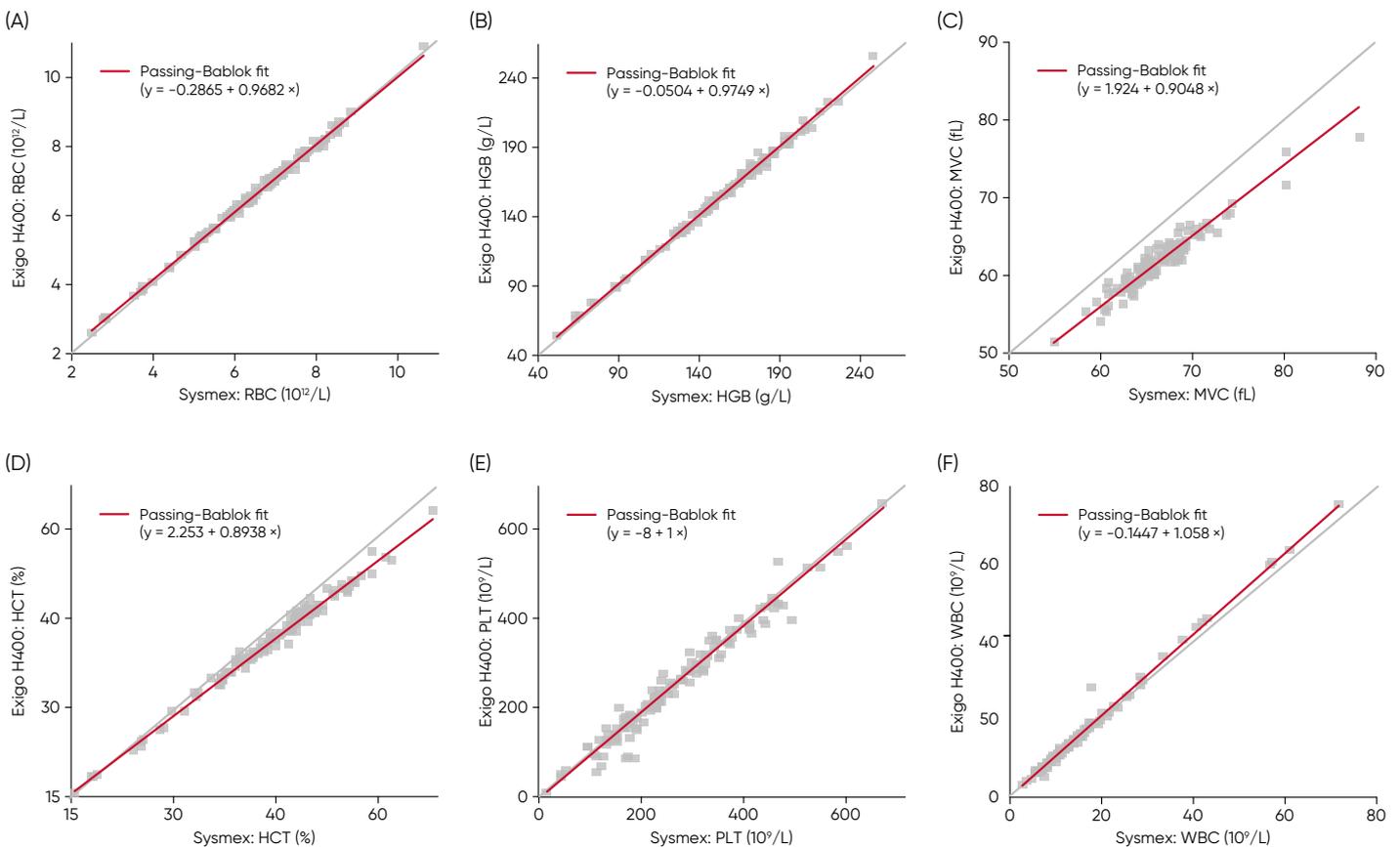


Fig 9. Agreement, using both unflagged and flagged dog samples, between Exigo H400 hematology system and a more advanced Sysmex™ XT-2000iV reference systems intended for the larger hospital laboratory. Correlation plots for (A) RBC, (B) HGB, (C) MCV, (D) HCT, (E) PLT, and (F) WBC. In the regression plots, the gray line corresponds to identity ($x = y$) and the red line corresponds to best fit.

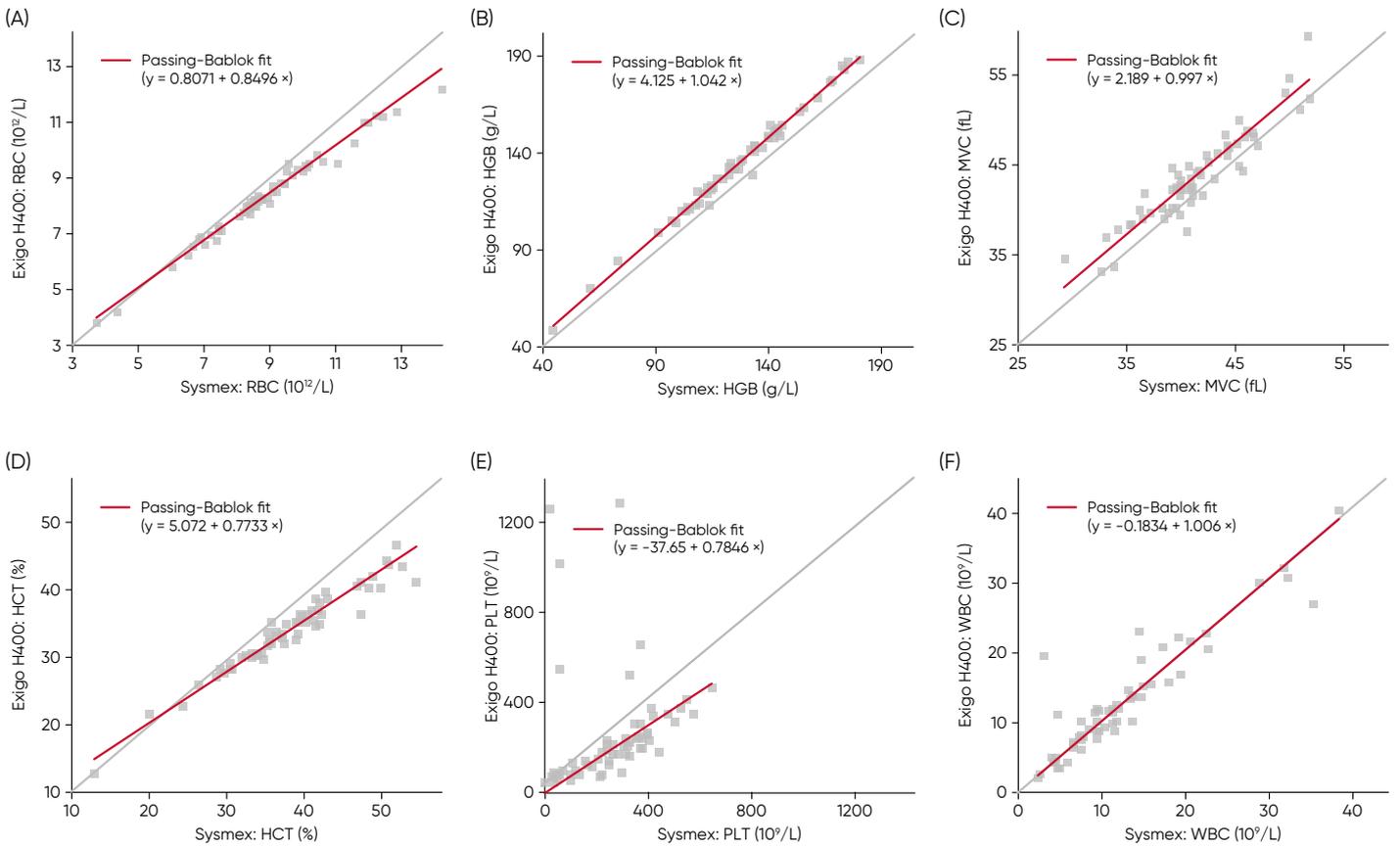


Fig 10. Agreement, using both unflagged and flagged cat samples, between Exigo H400 hematology system and a more advanced Sysmex XT-2000iV reference systems intended for the larger hospital laboratory. Correlation plots for (A) RBC, (B) HGB, (C) MCV, (D) HCT, (E) PLT, and (F) WBC. In the regression plots, the gray line corresponds to identity ($x = y$) and the red line corresponds to best fit.

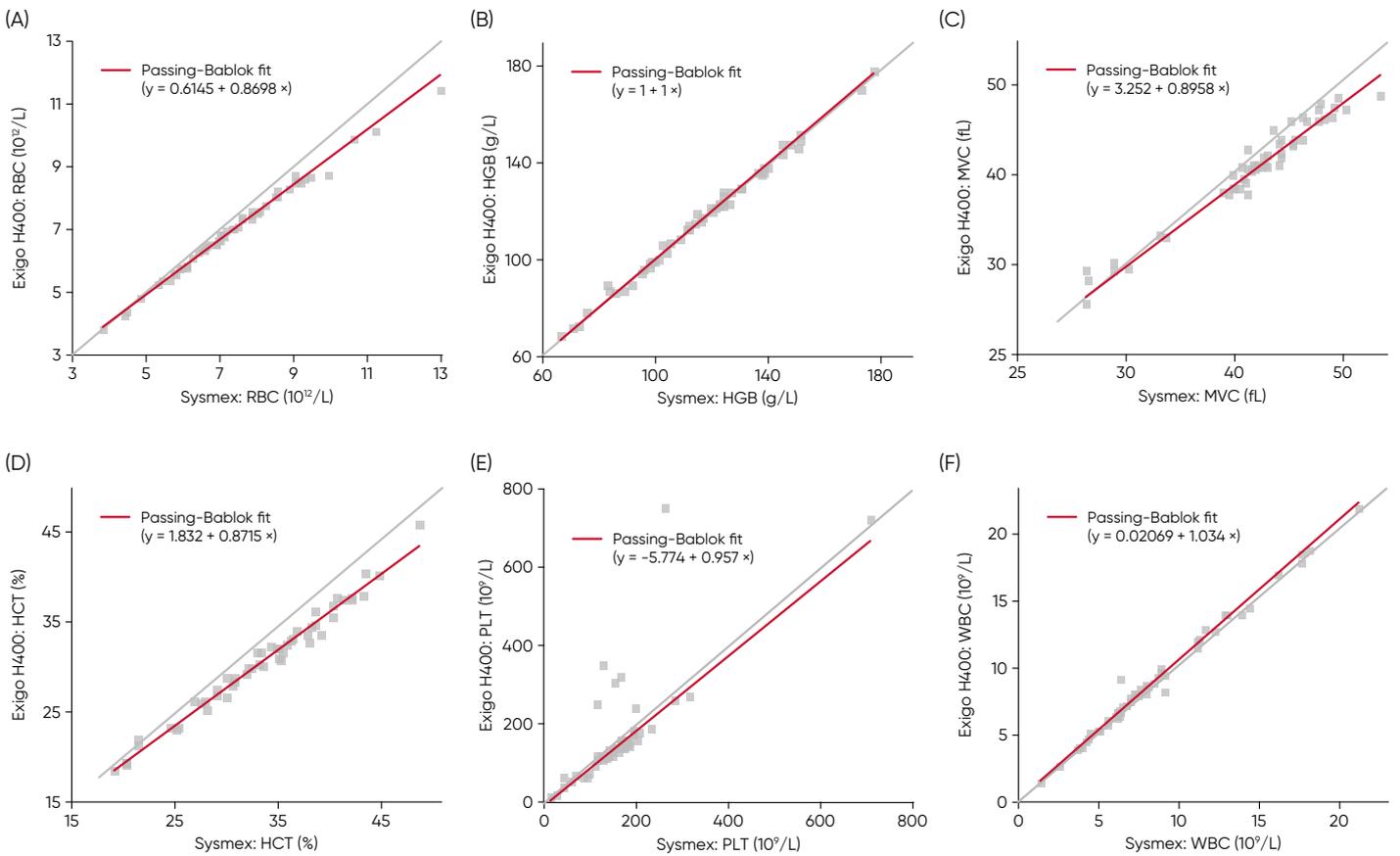


Fig 11. Agreement, using both unflagged and flagged horse samples, between Exigo H400 hematology system and a more advanced Sysmex XT-2000iV reference systems intended for the larger hospital laboratory. Correlation plots for (A) RBC, (B) HGB, (C) MCV, (D) HCT, (E) PLT, and (F) WBC. In the regression plots, the gray line corresponds to identity ($x = y$) and the red line corresponds to best fit.

Instrument maintenance

Designed with few moving parts, a maintenance-free closed shear valve design, and with the majority of the instrument cleaning procedures being automated, the user maintenance of Exigo H400 analyzer is kept to a minimum. However, some user intervention is still required. Section 10 "Analyzer care and maintenance" in the User manual contains information on how to maintain the Exigo H400 analyzer. An overview of maintenance procedures is given in Table 1.

Good practice also dictates keeping the instrument clean from dust and other impurities. Regularly, check if there is dust inside the instrument. At the same time, check that reagent connection or waste tubes are not bent or squeezed. Also, regularly check for possible leakages from components inside the instrument.

The system software monitors a number of system functions and will display information that alerts the operator to check the system or sample or initiate selected troubleshooting procedures.

Table 1. Scheduled maintenance

Procedure	Description	Frequency
Sample probe cleaning	Clean with paper tissue moistened with a 70% alcohol solution. Remove possible traces of salt crystals or blood at the top of the sample probe and probe rinse cup using a paper tissue moistened with the alcohol solution.	Daily
Surface cleaning	Gently clean the display and/or outside of the analyzer with a soft cloth, slightly moistened with water and a mild soap. Dry carefully.	When necessary
Clot prevention	Fill a small container with 5 mL of Enzymatic Cleaner from Boule Cleaning Kit. From Main Menu , press Maintenance and then press Clot Prevention . <ul style="list-style-type: none"> Hold the cleaner container under the OT probe, submerged in cleaner, press OK to confirm. Perform a background check to verify that all values are within range.	Every 1000 samples
Cleaning procedure	Select Main Menu , then Maintenance , and arrow over to next page to enter the Cleaning Menu . Follow instruction for use (IFU) for the Boule Cleaning Kit to clean the analyzer.	Less than 50 samples/day = every six months More than 50 samples/day = every three months 100–200 samples/day = every month.
Preventive maintenance (PM)	Inspection, and adjustments upon need, performed by an authorized service technician. PM kit available and included components should be exchange by an authorized service technician.	Every year or 20 000 samples

Quality control

Exigo H400 hematology analyzer is part of Boule's Total Quality Concept which is designed to increase the value of reported hematology results. Controls and calibrators are key elements of this initiative. Boule QC materials (Boule Con-Diff Vet and Boule Cal Vet) ensure that Exigo H400 performs accurately and delivers quality-controlled hematology results. Advanced quality control capabilities built into the Exigo H400 software include Mean, SD, CV, Levey-Jennings charts, and QC reports.

The analyzer has been factory calibrated prior to shipment. If necessary, however, a calibration functionality is available. Good laboratory practice dictates regular checks and calibration of the measured parameters. Only authorized operators can update or change calibration factors.

Specifications

19 parameters	<ul style="list-style-type: none"> • RBC, MCV, HCT, MCH, MCHC, RDW#, RDW%, HGB • PLT, MPV • WBC, LYM#, LYM%, MON#, MON%, GRA/NEU#, GRA/NEU%, EOS#, EOS% <p>Note: if EOS parameter is activated, NEU and EOS will be displayed instead of GRA/NEU</p>
Species	<p>12 pre-installed species profiles</p> <ul style="list-style-type: none"> • 4-part WBC differential with for dog, cat and horse • 3-part WBC differential for cattle, ferret, rabbit, sheep, rat, mouse, pig, goat and new world camel <p>Possibility of creating own profiles manually</p>
Throughput	Up to 53 samples/hour
Sample analysis	
Samples	Venous blood, capillary blood, pre-diluted
Sampling system	Closed shear valve, micro-capillary (MPA)
Sample volume	Open tube aspiration 110 µL, micro-capillary (MPA) 20 µL
Precision (open tube)	<p>CV WBC: ≤ 3.5%</p> <p>CV RBC: ≤ 1.8%</p> <p>CV MCV: ≤ 1.5%</p> <p>CV HGB: ≤ 1.5%</p> <p>CV PLT: ≤ 5.2%</p>
Precision (MPA)	<p>CV WBC: ≤ 4.0%</p> <p>CV RBC: ≤ 2.7%</p> <p>CV MCV: ≤ 1.5%</p> <p>CV HGB: ≤ 2.4%</p> <p>CV PLT: ≤ 5.2%</p>
Reagents	3 RFID-locked reagents are used for analysis: Exigo Diluent, Exigo Lyse, Exigo EOS Reagent
Display	7 inch TFT touch screen
Data storage capacity	Up to 50 000 samples
Interface ports	4 USB ports, 1 LAN port that supports LIS/HIS communication through HL7 protocol
Printout	Postscript-compatible printers supporting PCL 3/5e
Dimension (H × W × D)	395 × 295 × 475 mm
Weight	18 kg
Additional features	<p>Built-in mixer for 6 tubes of 3 different sizes</p> <p>Hematological Guidelines for pathological samples</p> <p>Control Assay Values scanned into system through barcode entry</p> <p>On board clot prevention system</p>

Ordering information

Product	Product code
Exigo H400	1420001
Exigo Diluent 10 L, RFID	1504504
Exigo Diluent 1.9 L, RFID	1504501
Exigo Lyse 1.9 L, RFID	1504500
Exigo Cleaner 1.9 L, RFID	1504503
Exigo EOS Lyse 1.9 L, RFID	1504502
Boule Cleaning Kit, 3 × 450 mL	1504111
Boule Enzymatic Cleaner, 100 mL	1504112
Boule Hypochlorite 2.0% Cleaner, 500 mL	1504113
Boule Vet Con Normal, 1 × 4.5 mL	1504026
Boule Vet Con Normal, 6 × 4.5 mL	1504027
Boule Vet Cal 1 × 3.0 mL	1504028

Related literature	Product code
User Manual: Exigo H400	1504496
Flyer: Exigo H400	38941
Quick Reference Guide Exigo H400	1504499

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