HemoCue® WBC

Operating Manual

Bedienungsanleitung

Manuel d'utilisation

Gebruiksaanwijzing

HemoCue®

A Quest Diagnostics Company

GB/US

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HemoCue® WBC system
HemoCue® WBC-System
Système HemoCue® WBC
HemoCue® WBC-systeem

GB/US

Thank you for choosing the HemoCue WBC system. The system is indicated for use for quantitative determination of white blood cell (WBC) count in capillary or venous whole blood. The HemoCue WBC system is for *In Vitro* Diagnostic use only. The HemoCue WBC Analyzer is only to be used with HemoCue WBC Microcuvettes. The HemoCue WBC system is indicated for use in clinical laboratories and for point-of-care settings.

All system components are designed and manufactured to provide maximum safety. Any other use of the system than indicated may impair the safety.

DE

Vielen Dank dafür, dass Sie sich für das HemoCue WBC-System entschieden haben. Das System dient der Bestimmung der Anzahl an weißen Blutkörperchen (WBK, englische Abkürzung WBC) in kapillarem oder venösem Vollblut. Das HemoCue WBC-System ist nur für den *In-Vitro*-diagnostischen Gebrauch bestimmt. Der HemoCue WBC Analyzer darf nur in Verbindung mit HemoCue WBC Microcuvettes verwendet werden. Das HemoCue WBC-System ist zur Verwendung in klinischen Laboratorien und im POCT vorgesehen.

Bei Entwicklung und Herstellung aller Systemkomponenten wird auf maximale Sicherheit geachtet. Wenn das System nicht wie angegeben verwendet wird, kann dies die Sicherheit beeinträchtigen.

FR

Merci d'avoir choisi le système HemoCue WBC. L'utilisation du système est indiquée pour déterminer la quantité de globules blancs (WBC – white blood cell) dans le sang capillaire ou le sang veineux total. Le système HemoCue WBC est destiné au diagnostic *in vitro* uniquement. L'appareil HemoCue WBC Analyzer doit être utilisé exclusivement avec les consommables HemoCue WBC Microcuvettes. Le système HemoCue WBC est utilisée en laboratoire ou directement au lit du patient.

Tous les composants du système sont conçus et fabriqués de manière à assurer une sécurité maximale. Tout autre usage du système peut entraîner un risque pour la sécurité.

NL

Hartelijk dank dat u gekozen hebt voor het HemoCue WBC-systeem. Het systeem is bedoeld voor de kwantitatieve bepaling van de leukocytentelling (WBC-telling) in capillair of veneus volbloed. Het HemoCue WBC-systeem is alleen bestemd voor *in-vitro* diagnostisch gebruik. De HemoCue WBC Analyzer mag alleen worden gebruikt met HemoCue WBC Microcuvettes. Het HemoCue WBC-systeem is bedoeld voor gebruik in klinische laboratoria en 'point-of-care'-situaties.

Alle systeemcomponenten zijn ontworpen en vervaardigd om maximale veiligheid te bieden. Als het systeem voor andere doeleinden wordt gebruikt dan is aangegeven, kan de veiligheid in gevaar komen.

Components
Bestandteile
Éléments
Onderdelen

GB/US

1. HemoCue WBC Analyzer*
2. AC adapter or
3. Six type AA batteries**
4. HemoCue WBC Microcuvettes**
5. HemoCue WBC Operating Manual, HemoCue WBC Quick Reference Guide and Instruction CD
6. HemoCue Cleaner

Open the carton and lift out the analyzer and accessories and place them on a stable surface (non-vibrating).

* Do not open the cover of the analyzer.

** Not included.
For infomation about HemoCue WBC Microcuvettes, please contact your HemoCue distributor.

DE

1. HemoCue WBC Analyzer*
2. Netzteil oder
3. Sechs AA-Batterien**
4. HemoCue WBC Microcuvettes**
5. HemoCue WBC Bedienungsanleitung, HemoCue WBC Kurzanleitung und Handbuch-CD
6. HemoCue Cleaner

Öffnen Sie den Karton, entnehmen Sie Analyzer und Zubehör und stellen Sie sie auf eine stabile Unterlage (nicht vibrierend).

* Die Abdeckung des Analyzers nicht öffnen.

** Nicht enthalten.
Informationen über HemoCue WBC Microcuvettes erhalten Sie von Ihrem HemoCue-Lieferanten.

FR

1. HemoCue WBC Analyzer*
2. Adaptateur secteur ou
3. 6 piles de type AA**
4. HemoCue WBC Microcuvettes**
5. Manuel d'utilisation HemoCue WBC, Guide de référence rapide et CD d'instructions HemoCue WBC
6. Tampon HemoCue Cleaner

Placer la boîte sur une surface stable (sans vibrations) pour l'ouvrir et sortir l'analyseur et ses accessoires.

* Ne pas ouvrir le boîtier de l'analyseur.

** Non fournis.
Pour plus d'informations sur les HemoCue WBC Microcuvettes, veuillez contacter votre distributeur HemoCue.

NL

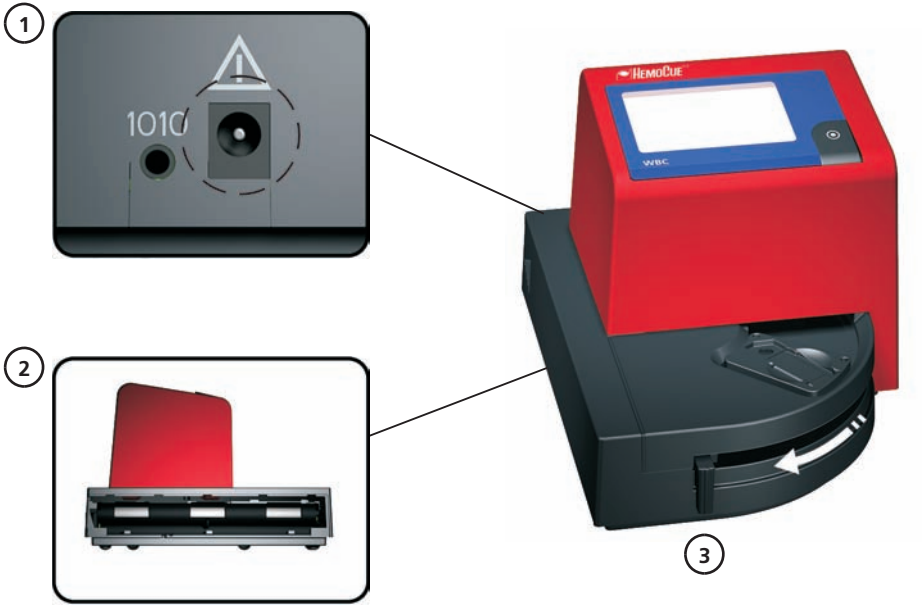
1. HemoCue WBC Analyzer*
2. Wisselstroomadapter of
3. 6 batterijen type AA**
4. HemoCue WBC Microcuvettes**
5. HemoCue WBC gebruiksaanwijzing, verkorte HemoCue WBC gebruiksaanwijzing en instructie-cd.
6. HemoCue Cleaner

Open de doos, neem de analyser en de accessoires uit de doos en plaats ze op een stabiele (niet-trillende) ondergrond.

* Maak het deksel van de analyser niet open.

** Niet meegeleverd.
Voor informatie over de HemoCue WBC Microcuvettes kunt u contact opnemen met uw HemoCue-leverancier.

Start up
Inbetriebnahme
Mise en service
Starten



GB/US

Only use adapters, as listed under Specifications, in the Adapters section.

1. If AC power is available, plug the supplied power adapter into the power inlet at the back of the Analyzer.
2. If no power is available, insert six type AA batteries, 1.5 V. To open the battery lid on the left side of the Analyzer, press on the ribbed marking engraved on the battery lid and slide it backwards until it opens. Gently take out the battery holder. Place the batteries in the battery holder observing the indication of polarity. Put the battery holder back in the battery compartment and close the lid. Consult local environmental authorities for proper disposal of batteries.
3. Pull the cuvette moving arm out to the loading position.

DE

Verwenden Sie nur die im Abschnitt Netzteile der Technischen Daten angegebenen Netzteile.

1. Wenn eine Wechselstromversorgung verfügbar ist, schließen Sie das mitgelieferte Netzteil an den Stromversorgungseingang an der Rückseite des Analyzers an.
2. Wenn keine Stromversorgung verfügbar ist, legen Sie die sechs AA-Batterien mit 1,5 V ein. Um den Deckel des Batteriefachs auf der linken Seite des Analyzers zu öffnen, drücken Sie auf die gerippte Markierung auf dem Batteriefachdeckel und schieben Sie ihn zurück, bis er sich öffnet. Nehmen Sie den Batteriehalter vorsichtig heraus. Legen Sie die Batterien in den Batteriehalter und beachten Sie dabei die Hinweise zur Polarität. Legen Sie den Batteriehalter wieder zurück ins Batteriefach und schließen Sie den Deckel. Beachten Sie die örtlichen Bestimmungen zur ordnungsgemäßen Entsorgung von Batterien.
3. Ziehen Sie dann den beweglichen Küvettenarm in die Ladeposition heraus.

FR

Utiliser uniquement les adaptateurs mentionnés dans la liste des caractéristiques, section Adaptateurs.

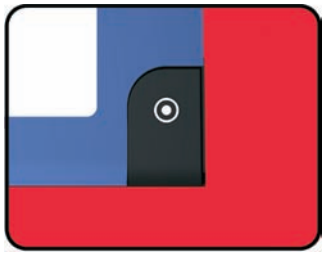
1. Si l'alimentation secteur est disponible, brancher l'adaptateur secteur fourni dans la prise située à l'arrière de l'analyseur.
2. S'il n'y a pas d'alimentation secteur, insérer six piles de type AA, à 1,5 V. Pour ouvrir le compartiment des piles, situé sur la gauche de l'analyseur, appuyer sur la marque gravée du capot et le faire glisser vers l'arrière. Retirer doucement le support des piles. Placer les piles dans le support, en respectant la polarité. Replacer le support dans le compartiment et fermer le capot. Consulter les autorités locales compétentes en matière d'environnement pour la mise au rebut adéquate des piles.
3. Extraire le bras mobile de la cuvette dans sa position de charge.

NL

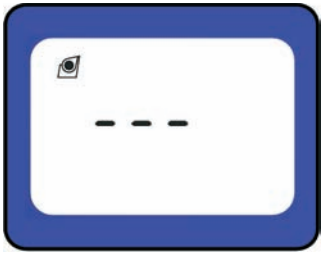
Gebruik alleen adapters zoals vermeld onder 'Specificaties' in het hoofdstuk 'Adapters'.

1. Als er netvoeding beschikbaar is, sluit u de netadapter aan op de stroomaansluiting op de achterkant van de analyser.
2. Plaats, als er geen netvoeding beschikbaar is, zes batterijen van het type AA van 1,5 V. U opent het batterijdeksel aan de linkerkant van de analyser door te drukken op de geribbelde markering op het batterijdeksel en dit naar achteren te schuiven totdat het is geopend. Neem de batterijhouder er voorzichtig uit. Plaats de batterijen in de batterijhouder en let daarbij op de juiste richting van de batterijpolen. Plaats de batterijhouder terug in het batterijvak en sluit het deksel. Neem de geldende milieuvoorschriften in acht wanneer u oude batterijen weggooit.
3. Trek de cuvettehouder uit naar de laadpositie.

4



4



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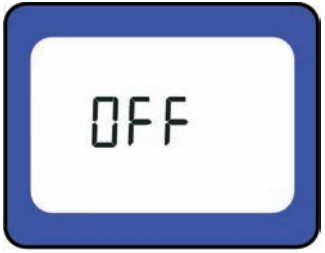


GB/US

4. Press and hold the button until the display is activated (all symbols appear on the display). The Analyzer performs a self test, and after approximately 10 seconds the display will show three flashing dashes and the HemoCue symbol. This indicates that the Analyzer is ready for use.
5. If the cuvette moving arm is in the measuring position, the most recent result will be displayed.
6. To turn the Analyzer off, press and hold the button until the display reads OFF and then goes blank. If the Analyzer is operating on battery power, but not being used, it will automatically turn off after approximately five minutes and if operating on AC power, it will turn off after two hours.

DE

4. Halten Sie die Taste gedrückt, bis die Anzeige aktiviert wird (alle Symbole werden auf dem Display angezeigt). Der Analyzer führt einen Selbsttest aus und nach ca. 10 Sekunden werden auf dem Display drei blinkende Striche sowie das HemoCue-Symbol angezeigt. Dies zeigt an, dass der Analyzer einsatzbereit ist.
5. Wenn sich der bewegliche Küvettenarm in der Messposition befindet, wird das letzte Ergebnis angezeigt.
6. Zum Ausschalten des Analyzers halten Sie die Taste gedrückt, bis auf der Anzeige zunächst „OFF" und dann gar nichts mehr angezeigt wird. Wenn der Analyzer über Batterien betrieben jedoch nicht verwendet wird, schaltet er sich nach etwa 5 Minuten automatisch aus. Wenn er über das Netzteil betrieben wird, schaltet er sich nach zwei Stunden aus.

FR

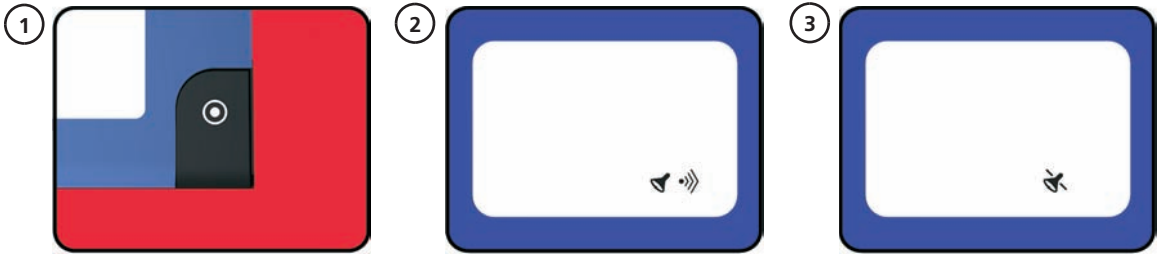
4. Appuyer sur la touche et la maintenir enfoncée jusqu'à l'activation de l'écran (tous les symboles s'affichent). L'analyseur effectue un autocontrôle. Au bout de 10 secondes environ, trois tirets clignotants et le symbole HemoCue apparaissent à l'écran. Cela indique que l'analyseur est prêt à l'emploi.
5. Si le bras mobile de la cuvette est en position de mesure, le résultat le plus récent s'affiche.
6. Pour éteindre l'analyseur, appuyer sur la touche et maintenir la pression jusqu'à ce que l'écran affiche OFF et s'éteigne. L'analyseur s'arrête automatiquement lorsqu'il fonctionne sur piles et qu'il n'est pas utilisé pendant cinq minutes. En cas de branchement secteur, il s'éteint au bout de deux heures.

NL

4. Druk op de knop en houd deze ingedrukt totdat het display is geactiveerd (alle symbolen verschijnen op het display). De analyser voert een zelftest uit. Na ongeveer 10 seconden toont het display drie knipperende streepjes en het HemoCue-symbool. Dit geeft aan dat de analyser gereed is voor gebruik.
5. Als de cuvettehouder zich in de meetpositie bevindt, wordt het meest recente resultaat getoond.
6. Om de analyser uit te zetten, drukt u op de knop en houdt u deze ingedrukt totdat in het display OFF verschijnt en het display vervolgens wordt uitgeschakeld. Als de analyser op batterijen werkt, maar niet wordt gebruikt, zal deze na ongeveer vijf minuten automatisch worden uitgeschakeld. Als de analyser op de netvoeding werkt, zal de analyser na twee uur worden uitgeschakeld.

Set-up
Einstellung
Configuration
Set-up

Audio signal
Tonsignal
Signal sonore
Geluidssignaal



GB/US

If the audible signal is activated, a signal will be heard when the measurement is completed, or if an error code is displayed. To activate or deactivate the audible signal, follow the steps below.

1. Make sure that the analyzer is turned off. Press the button for approximately 10 seconds.
2. The display now shows a flashing bell symbol.
3. Press the button rapidly to change between signal on and off.

When the setting is completed, press the button for approximately 3 seconds until the bell stops flashing. The analyzer will return to the ready mode.

DE

Bei aktiviertem Tonsignal wird ein Tonsignal ausgegeben, wenn eine Messung abgeschlossen ist oder wenn ein Fehlercode angezeigt wird. Um das Signal zu aktivieren oder zu deaktivieren folgen Sie den folgenden Schritten.

1. Vergewissern Sie sich, dass der Analyzer ausgeschaltet ist. Halten Sie die Taste etwa 10 Sekunden lang gedrückt.
2. In der Anzeige erscheint ein blinkendes Tonsymbol.
3. Drücken Sie schnell die Taste, um die Ausgabe des Tonsignals ein- bzw. auszuschalten.

Wenn Sie die Einstellung vorgenommen haben, halten Sie die Taste etwa 3 Sekunden gedrückt, bis das Tonsymbol nicht mehr blinkt. Der Analyzer wechselt dann wieder in den Bereit-Modus.

FR

Si le signal sonore est activé, un signal sera émis à l'issue de la mesure, ou en cas d'affichage d'un code d'erreur. Procéder comme suit pour activer ou désactiver le signal sonore.

1. S'assurer que l'analyseur est hors tension. Appuyer sur la touche pendant environ 10 secondes.
2. L'écran affiche un symbole de cloche clignotant.
3. Appuyer rapidement sur la touche pour activer/désactiver le signal sonore.

À l'issue des réglages, appuyer sur la touche pendant environ 3 secondes jusqu'à ce que la cloche arrête de clignoter. L'analyseur se remet automatiquement en position de mesure.

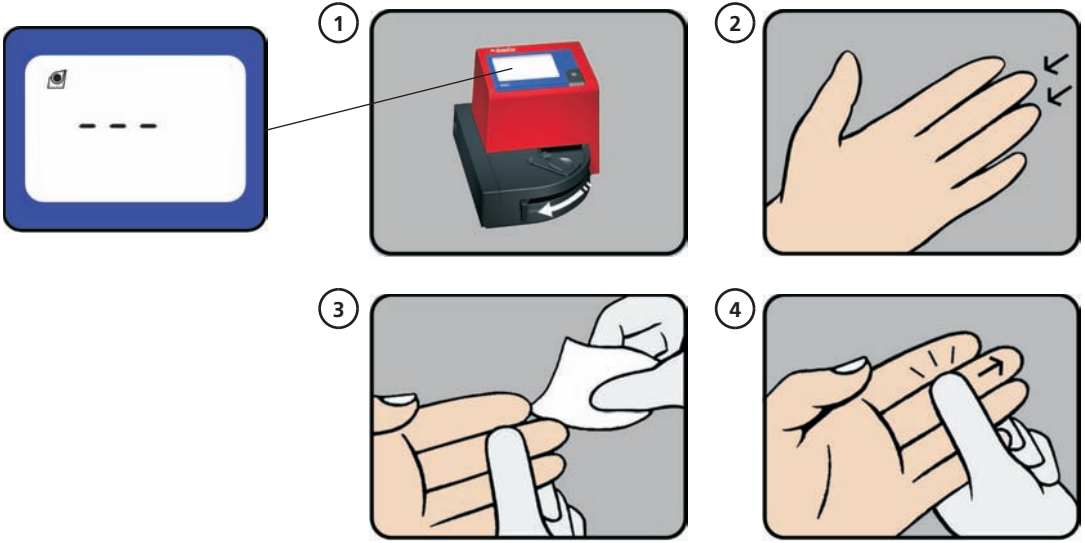
NL

Als het geluidssignaal is geactiveerd, klinkt het signaal wanneer de meting is voltooid of wanneer een foutmelding wordt weergegeven. Voer de onderstaande stappen uit om het geluidssignaal te activeren of deactiveren.

1. Controleer of de analyser uitgeschakeld is. Houd de knop ongeveer 10 seconden ingedrukt.
2. In het display verschijnt een knipperend kloksymbool.
3. Druk snel op de knop om het signaal in of uit te schakelen.

Als de instelling is voltooid, drukt u ongeveer 3 seconden op de knop totdat het symbool niet meer knippert. De analyser keert nu terug naar de Gereed-modus.

Measuring Capillary blood
Messung Kapillarblut
Mesure Sang capillaire
Meting Capillair bloed



GB/US

Always handle blood specimens with care, as they might be infectious. Consult local environmental authorities for proper disposal. Always wear protective gloves when handling blood specimens. The microcuvette is for single use only.

1. To perform a test, the cuvette moving arm should be in its loading position. The display will show three flashing dashes and the HemoCue symbol. Take a HemoCue WBC Microcuvette from the vial.
2. Make sure the patient's hand is warm and relaxed. Use only the middle or ring finger for sampling. Avoid fingers with rings on.
3. Clean fingertip with disinfectant and allow to dry completely or wipe off with a dry, lint-free wipe.
4. Using your thumb, lightly press the finger from the top of the knuckle towards the tip.

DE

Gehen Sie stets sorgsam mit Blutproben um, da diese infektiös sein könnten. Zur ordnungsgemäßen Entsorgung beachten Sie die Bestimmungen der örtlichen Umweltbehörde. Tragen Sie beim Umgang mit Blutproben stets Schutzhandschuhe. Die Mikroküvetten sind nur zur einmaligen Verwendung vorgesehen.

1. Zur Durchführung eines Tests sollte sich der bewegliche Küvettenarm in seiner Ladeposition befinden. Auf der Anzeige erscheinen drei blinkende Striche und das HemoCue-Symbol. Nehmen Sie eine HemoCue WBC Microcuvette aus der Dose.
2. Stellen Sie sicher, dass die Hand des Patienten warm und entspannt ist. Verwenden Sie für die Probenentnahme nur den Mittel- oder Ringfinger. Achten Sie darauf, dass sich am Finger kein Ring befindet.
3. Reinigen Sie die Fingerkuppe mit einem Desinfektionsmittel. Warten Sie, bis sie wieder ganz trocken ist, oder wischen Sie sie mit einem trockenen, fusselfreien Tuch ab.
4. Drücken Sie den Finger mit Ihrem Daumen mit leichtem Druck vom Knöchel zur Spitze hin.

FR

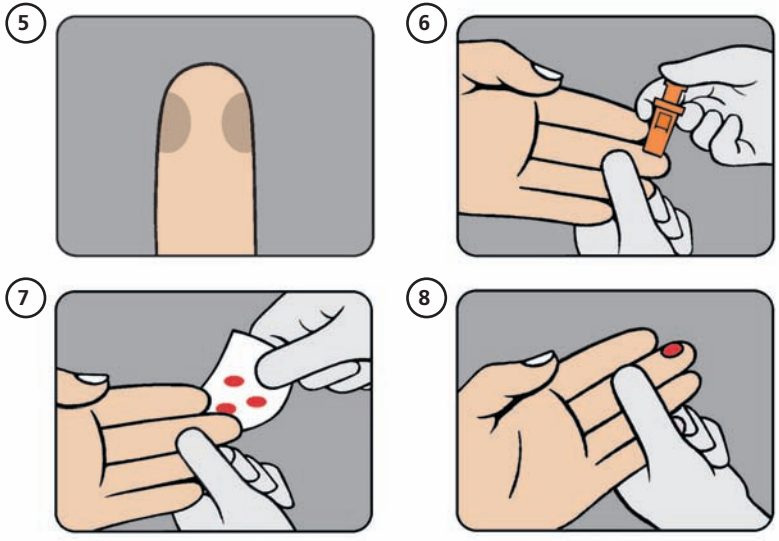
Pour éviter tout risque de contamination, il est recommandé de manipuler les échantillons de sang avec la plus grande précaution. Consulter les autorités locales compétentes en matière d'environnement pour connaître les méthodes d'élimination adéquates. Toujours mettre des gants de protection avant de manipuler des échantillons de sang. La microcuvette est à usage unique.

1. Pour effectuer un test, le bras mobile de la cuvette doit se trouver en position de charge. Trois tirets clignotants et le symbole HemoCue apparaissent à l'écran. Retirer le consommable HemoCue WBC Microcuvette du flacon.
2. S'assurer que la main du patient est chaude et détendue. Le prélèvement devra être effectué sur le majeur ou l'annulaire. Éviter les doigts portant des bagues.
3. Nettoyer l'extrémité du doigt avec un désinfectant et laisser sécher ou essuyer avec un chiffon sec et non pelucheux.
4. Avec le pouce, presser doucement le doigt, de l'articulation vers l'extrémité.

NL

Behandel bloedmonsters altijd voorzichtig, aangezien deze mogelijk infectieus zijn. Neem de geldende milieuvoorschriften in acht bij het afvoeren van afval. Draag altijd beschermende handschoenen tijdens het werken met bloedmonsters. De microcuvette is bestemd voor eenmalig gebruik.

1. Om een test met capillair bloed uit te voeren, moet de cuvettehouder zich in de laadpositie bevinden. In het display verschijnen drie knipperende streepjes en het HemoCue-symbool. Neem een HemoCue WBC Microcuvette uit de verpakking.
2. Zorg dat de hand van de patiënt warm en ontspannen is. Gebruik alleen de middel- of ringvinger voor het nemen van een monster. Vermijd vingers met een ring.
3. Maak de vingertop schoon met een desinfecterend middel en laat de vingertop volledig drogen of veeg deze af met een droge, pluisvrije doek.
4. Druk met uw duim licht op de vinger vanaf de bovenzijde van de knokkel in de richting van de vingertop.


5
6
7
8

GB/US

5. Sample at the side of the fingertip.
6. While applying light pressure towards the fingertip, puncture the finger using a lancet*.
7. Wipe away the first two or three drops of blood.
8. Re-apply light pressure towards the fingertip until another drop of blood appears.

* Spring loaded lancets with a puncture depth of at least 2 mm are prefered to produce a sufficient blood flow.

DE

5. Nehmen Sie die Blutprobe seitlich an der Fingerspitze.
6. Drücken Sie leicht zur Fingerspitze hin und punktieren Sie den Finger mit einer Lanzette*.
7. Wischen Sie die ersten zwei oder drei Bluttropfen ab.
8. Drücken Sie wieder leicht zur Fingerspitze hin, bis ein weiterer Bluttropfen austritt.

* Lanzetten, die durch eine Feder vorgespannt sind und eine Einstichtiefe von mindestens 2 mm haben, werden bevorzugt, um eine ausreichenden Blutfluss zu erzielen.

FR

5. Prélever l'échantillon sur la face latérale de l'extrémité du doigt.
6. En pressant doucement vers l'extrémité du doigt, piquer le point de prélèvement avec une lancette*.
7. Essuyer les deux ou trois premières gouttes de sang.
8. Exercer de nouveau une légère pression sur l'extrémité du doigt pour faire apparaître une nouvelle goutte de sang.

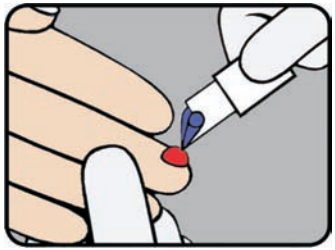
* Des lancettes à ressort d'une profondeur de prélèvement d'au moins 2 mm sont préférables pour obtenir un flux sanguin suffisant.

NL

5. Neem het monster aan de zijkant van de vingertop af.
6. Oefen een lichte druk uit in de richting van de vingertop en prik in de vinger met een lancet*.
7. De eerste 2 of 3 druppels bloed wegvegen.
8. Handhaaf de lichte druk in de richting van de vingertop tot er een volgende druppel bloed verschijnt.

* Gebruik voor voldoende bloedstroom bij voorkeur lancetten met een veer, die een punctiediepte hebben van minstens 2 mm.

9



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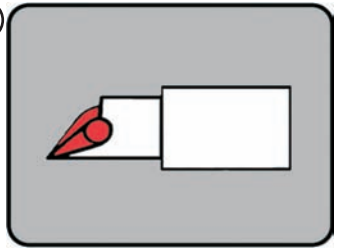
11



GB/US

9. When the blood drop is large enough, fill the microcuvette in one continuous process. Do NOT refill! NOTE: Make sure that the microcuvette is filled from the tip, placed at about a 45 degree angle towards the blood drop according to the picture on page 18.
10. Wipe off excess blood from the outside of the microcuvette with a clean, lint-free wipe. Do not touch the open end of the microcuvette.
11. Look for air bubbles in the filled microcuvette. If present, discard the microcuvette and fill a new microcuvette from a new drop of blood. Small bubbles around the edge can be ignored. NOTE: Make sure that the microcuvette is filled according to picture 9 on page 18 since an improper filling angle might cause air bubbles to be introduced.

NOTE: If a second sample is to be taken, it is important that this is done after the measurement of the first sample is complete. Wipe away the remains of the drop of blood and fill the second microcuvette from a new drop of blood as per steps 7–11 above.

DE

9. Wenn der Bluttropfen groß genug ist, füllen Sie die Mikroküvette ohne abzusetzen. Die Küvette darf NICHT nachbefüllt werden! HINWEIS: Stellen Sie sicher, dass die Mikroküvette von der Spitze aus gefüllt wird, die ungefähr in einem 45-Grad-Winkel zu dem Bluttropfen gehalten wird, siehe Bild auf Seite 18.
10. Wischen Sie überschüssiges Blut außen an der Mikroküvette mit einem sauberen, fusselfreien Tuch ab, ohne dabei die Öffnung der Küvette zu berühren.
11. Überprüfen Sie die gefüllte Küvette auf Luftblasen. Sollten Luftblasen vorhanden sein, entsorgen Sie die Mikroküvette und füllen Sie eine neue Mikroküvette mit einem neuen Tropfen Blut. Kleinere Luftbläschen an den Rändern sind ohne Bedeutung. HINWEIS: Stellen Sie sicher, dass die Mikroküvette gemäß Bild 9 auf Seite 18 gefüllt wird, da ein nicht ordnungsgemäßer Füllwinkel zum Einziehen von Luftblasen führen könnte.

HINWEIS: Wenn eine zweite Probe entnommen werden soll, achten Sie darauf, dass dies erst erfolgen darf, nachdem die Messung der ersten Probe abgeschlossen ist. Wischen Sie Reste des Bluttropfens weg und füllen Sie die zweite Mikroküvette aus einem neuen Bluttropfen, wie in den Schritten 7–11 oben beschrieben.

FR

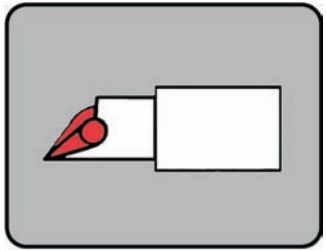
9. Quand la goutte de sang est assez grande, laisser la microcuvette se remplir d'un seul trait. NE JAMAIS la remplir une seconde fois ! REMARQUE : vérifier que l'extrémité de la microcuvette est placée à un angle d'environ 45 degrés vers la goutte de sang, comme sur l'image de la page 18.
10. Nettoyer la surface externe de la microcuvette pour éliminer toute trace de sang à l'aide d'un chiffon propre et non pelucheux. Ne pas toucher l'extrémité ouverte de la microcuvette.
11. Vérifier que la microcuvette remplie ne contient pas de bulles d'air. S'il y en a, jeter la microcuvette et prélever un nouvel échantillon avec une nouvelle microcuvette. De petites bulles d'air en périphérie peuvent être ignorées. REMARQUE : bien remplir la microcuvette conformément à l'image 9 de la page 18. Un angle de remplissage inadapté pourrait entraîner l'introduction de bulles d'air.

REMARQUE : si un second échantillon doit être prélevé, il est important de le faire après avoir terminé la mesure du premier. Nettoyer les restes de la goutte de sang et remplir la seconde microcuvette d'une nouvelle goutte de sang en suivant les étapes 7 à 11 qui précèdent.

NL

9. Als de druppel groot genoeg is, de microcuvette in één keer vullen. NOOIT bijvullen. OPMERKING: Zorg ervoor dat de microcuvette vanuit de top wordt gevuld en in een hoek van ongeveer 45 graden ten opzichte van de druppel staat (zie de afbeelding op pagina 18).
10. Veeg het overtollige bloed van de buitenkant van de microcuvette weg met een schone, pluisvrije doek. Raak het open uiteinde van de microcuvette niet aan.
11. Controleer de gevulde microcuvette op luchtbellen. Als er luchtbellen zijn, dient u de microcuvette weg te gooien en een nieuw exemplaar met een nieuwe druppel bloed te vullen. Kleine belletjes tegen de rand kunnen worden genegeerd. OPMERKING: Zorg ervoor dat de microcuvette wordt gevuld zoals in afbeelding 9 op pagina 18 is te zien, omdat door het vullen in een onjuiste hoek luchtbellen in de microcuvette kunnen komen.

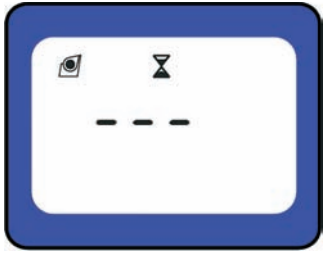
OPMERKING: Als u een tweede monster moet nemen, dient u altijd eerst de meting van het eerste monster te voltooien. Veeg de restanten van de druppel bloed weg en vul een tweede microcuvette met een nieuwe druppel bloed, zoals hierboven beschreven in de stappen 7–11.



12

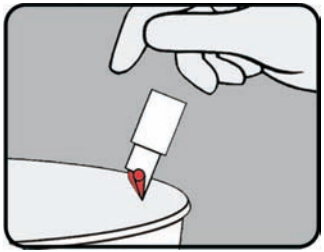
13

14



15

16



GB/US

12. Place the filled microcuvette in the cuvette holder within 40 seconds after filling.
13. Gently push the cuvette moving arm towards the measuring position. It will automatically slide to the measuring position and the measurement starts.
14. During the measurement "⌛", three fixed dashes and the HemoCue symbol will be shown.
15. After approximately 3 minutes, the WBC value is displayed. The result will remain on the display as long as the cuvette moving arm is in the measuring position. Do not remeasure the filled microcuvette.
16. Always handle blood specimens with care, as they might be infectious. Consult local environmental authorities for proper disposal.

DE

12. Setzen Sie die gefüllte Mikroküvette innerhalb von 40 Sekunden nach dem Füllen in den Küvettenhalter ein.
13. Schieben Sie den beweglichen Küvettenarm vorsichtig in Richtung der Messposition. Er gleitet automatisch in die Messposition und die Messung beginnt.
14. Während der Messung erscheinen „⌛", drei feststehende Striche und das HemoCue-Symbol.
15. Nach etwa 3 Minuten wird der WBK-Wert angezeigt. Das Ergebnis bleibt im Display stehen, so lange sich der bewegliche Küvettenarm in der Messposition befindet. Die gefüllte Mikroküvette kann nicht ein zweites Mal gemessen werden.
16. Gehen Sie stets sorgsam mit Blutproben um, da diese infektiös sein könnten. Zur ordnungsgemäßen Entsorgung beachten Sie die Bestimmungen der örtlichen Umweltbehörde.

FR

12. Placer la microcuvette remplie dans le support de cuvette dans les 40 secondes qui suivent le remplissage.
13. Pousser doucement le bras mobile de la cuvette en position de mesure. Il glissera automatiquement en position de mesure. La mesure démarre.
14. Au cours de la mesure « ⌛ », trois tirets et le symbole HemoCue apparaissent à l'écran.
15. Au bout de 3 minutes environ, le taux de globules blancs s'affiche. Le résultat reste affiché tant que le bras mobile de la cuvette est maintenu en position de mesure. Ne pas effectuer de nouvelle mesure avec la microcuvette remplie.
16. Pour éviter tout risque de contamination, il est recommandé de manipuler les échantillons de sang avec la plus grande précaution. Consulter les autorités locales compétentes en matière d'environnement pour connaître les méthodes d'élimination adéquates.

NL

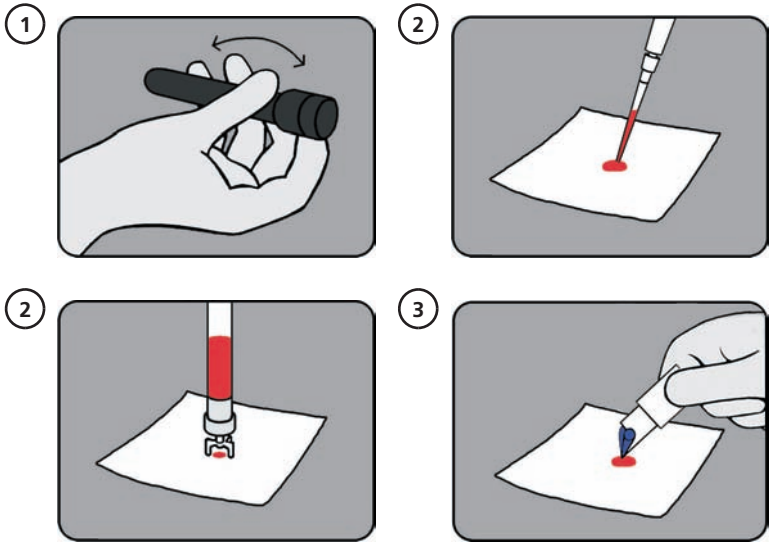
12. Plaats de gevulde microcuvette in de cuvettehouder. Dit dient binnen 40 seconden na het vullen van de cuvette te gebeuren!
13. Duw de cuvettehouder voorzichtig naar de laadpositie. De houder schuift automatisch door naar de laadpositie, waarna de meting begint.
14. Tijdens de meting ziet u in het display '⌛', drie niet-knipperende streepjes en het HemoCue-symbool.
15. De WBC-waarde verschijnt na ongeveer 3 minuten. Het resultaat blijft zichtbaar zolang de cuvettehouder zich in de meetpositie bevindt. Meet de gevulde microcuvette niet opnieuw.
16. Behandel bloedmonsters altijd voorzichtig, aangezien deze mogelijk infectieus zijn. Neem de geldende milieuvoorschriften in acht bij het afvoeren van afval.

Measuring Control material or venous blood

Messung Kontrollmaterial oder venöses Blut

Mesure Solution de contrôle ou sang veineux

Meting Controlemateriaal of veneus bloed



GB/US

Always handle blood specimens with care, as they might be infectious. Consult local environmental authorities for proper disposal. Always wear protective gloves when handling blood specimens. The microcuvette is for single use only.

1. If the venous blood samples has been stored in a refrigerator, allow it to warm up to room temperature (15–35 °C, 59–95 °F) before mixing. Mix the venous sample tubes thoroughly on a mechanical mixer for at least 2 minutes or invert the tube 10–20 times by hand.
   For control materials always follow instructions for use provided by the manufacturer.
2. Place a drop of blood or control material onto a hydrophobic plastic or glass slide using a pipette or other suitable transfer device.
3. Fill the microcuvette in one continuous process. Do NOT refill! NOTE: Make sure that the microcuvette is filled from the tip, placed at about a 45 degree angle towards the blood drop according to the picture on page 22.

Perform the analysis as per steps 10–16 on page 19–21.

DE

Gehen Sie stets sorgsam mit Blutproben um, da diese infektiös sein könnten. Zur ordnungsgemäßen Entsorgung beachten Sie die Bestimmungen der örtlichen Umweltbehörde. Tragen Sie beim Umgang mit Blutproben stets Schutzhandschuhe. Die Mikroküvetten sind nur zur einmaligen Verwendung vorgesehen.

1. Falls die venösen Blutproben im Kühlschrank aufbewahrt wurden, müssen sie vor dem Mischen Raumtemperatur erreichen (15–35 °C). Mischen Sie die Probe mit einem mechanischen Mixer mindestens 2 Minuten oder wenden Sie das Röhrchen 10–20 Mal hin und her. Befolgen Sie bei Kontrollmaterialien immer die Bedienungsanleitung des Herstellers.
2. Bringen Sie mit einer Pipette oder einem anderen geeigneten Hilfsmittel einen Tropfen Blut oder Kontrollmaterial auf einen hydrophoben Objektträger aus Kunststoff oder Glas auf.
3. Befüllen Sie die Küvette in einem Zug. Die Küvette darf NICHT nachbefüllt werden! HINWEIS: Stellen Sie sicher, dass die Mikroküvette von der Spitze aus gefüllt wird, die ungefähr in einem 45-Grad-Winkel zu dem Bluttropfen gehalten wird, siehe Bild auf Seite 22.

Führen Sie nun die Analyse entsprechend den Schritten 10–16 auf den Seiten 19–21 durch.

FR

Pour éviter tout risque de contamination, il est recommandé de manipuler les échantillons de sang avec la plus grande précaution. Consulter les autorités locales compétentes en matière d'environnement pour connaître les méthodes d'élimination adéquates. Toujours mettre des gants de protection avant de manipuler des échantillons de sang. La microcuvette est à usage unique.

1. Si les échantillons de sang veineux ont été stockés au réfrigérateur, les laisser atteindre la température ambiante (de 15 à 35 °C) avant de procéder au mélange. Mélanger les tubes d'échantillon de sang veineux sur un mélangeur mécanique pendant au moins 2 minutes ou retourner les tubes 10 à 20 fois à la main. Pour les solutions de contrôle, toujours respecter les instructions d'emploi du fabricant.
2. Placer une goutte de sang ou de solution de contrôle sur une surface hydrophobe, par exemple une plaque en plastique ou en verre, en utilisant une pipette ou un autre dispositif de transfert.
3. Remplir la microcuvette d'un seul trait. NE JAMAIS la remplir une seconde fois ! REMARQUE : vérifier que l'extrémité de la microcuvette est placée à un angle d'environ 45 degrés vers la goutte de sang, comme sur l'image de la page 22.

Effectuer l'analyse en suivant les étapes 10 à 16, décrites pages 19 à 21.

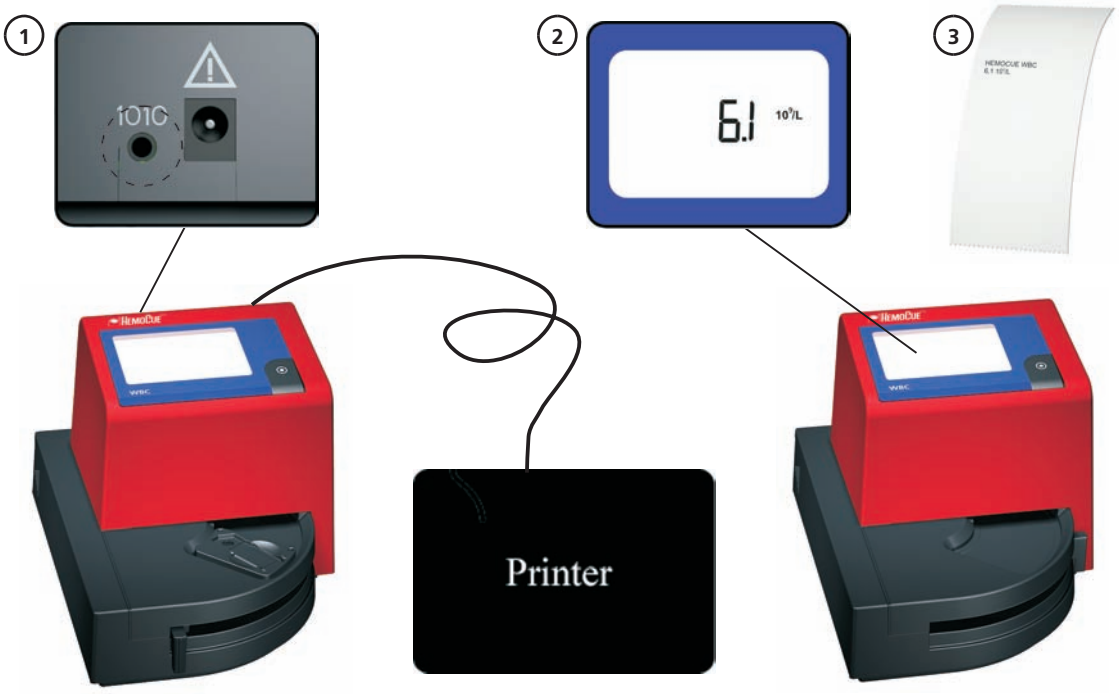
NL

Behandel bloedmonsters altijd voorzichtig, aangezien deze mogelijk infectieus zijn. Neem de geldende milieuvoorschriften in acht bij het afvoeren van afval. Draag altijd beschermende handschoenen tijdens het werken met bloedmonsters. De microcuvette is bestemd voor eenmalig gebruik.

1. Als het monster veneus bloed in een koelkast is bewaard, dient het eerst op kamertemperatuur (15–35 °C) te komen voordat het wordt gemengd. Meng de buizen met het monster van veneus bloed gedurende ten minste twee minuten grondig in een mechanische mixer of keer de buis 10–20 keer verticaal met de hand. Volg voor controlemateriaal altijd de instructies die de fabrikant heeft geleverd.
2. Breng met een pipet of ander geschikt overbrengingsmiddel een druppel bloed of controlemateriaal aan op een hydrofobe ondergrond, bijv. plastic folie.
3. Vul de microcuvette in één keer. NOOIT bijvullen. OPMERKING: Zorg ervoor dat de microcuvette vanuit de top wordt gevuld en in een hoek van ongeveer 45 graden ten opzichte van de druppel staat (zie de afbeelding op pagina 22).

Voer de meting uit zoals beschreven in stappen 10–16 op pagina 19–21.

Set-up Printer function
Einstellung Druckerfunktion
Configuration Mode impression
Set-up Printerfunctie



GB/US

Only the current result can be transferred to the printer directly after the measurement.

1. Connect the cable* to the analyzer and ASCII printer* before performing the analysis.
2. Perform the analysis.
3. When the result is shown on the display, it will be printed automatically.

* Not included.

The following comport settings are used

Baud rate	9600
Databits	8
Parity	None
Stopbits	1
Flowcontrol	None

DE

Nur das aktuelle Ergebnis kann unmittelbar nach der Messung an den Drucker übertragen werden.

1. Bevor Sie die Analyse durchführen, schließen Sie das Kabel* an Analyzer und ASCII-Drucker* an.
2. Führen Sie die Analyse durch.
3. Sobald das Ergebnis auf dem Display angezeigt wird, wird es automatisch ausgedruckt.

* Nicht enthalten.

Für den COM-Anschluss werden die folgenden Einstellungen verwendet:

Baudrate	9600
Datenbits	8
Parität	keine
Stoppbits	1
Flusskontrolle	keine

FR

Seul le résultat le plus récent peut être imprimé directement après la mesure.

1. Brancher le câble* entre l'analyseur et l'imprimante ASCII* avant d'effectuer l'analyse.
2. Effectuer l'analyse.
3. Lorsque le résultat est affiché à l'écran, il est automatiquement imprimé.

* Non fournis.

Les paramètres de composition suivants sont utilisés :

Débit en bauds	9600
Bits de données	8
Parité	Aucune
Bits d'arrêt	1
Contrôle de flux	Aucune

NL

Alleen het huidige resultaat kan direct na de bepaling worden uitgeprint.

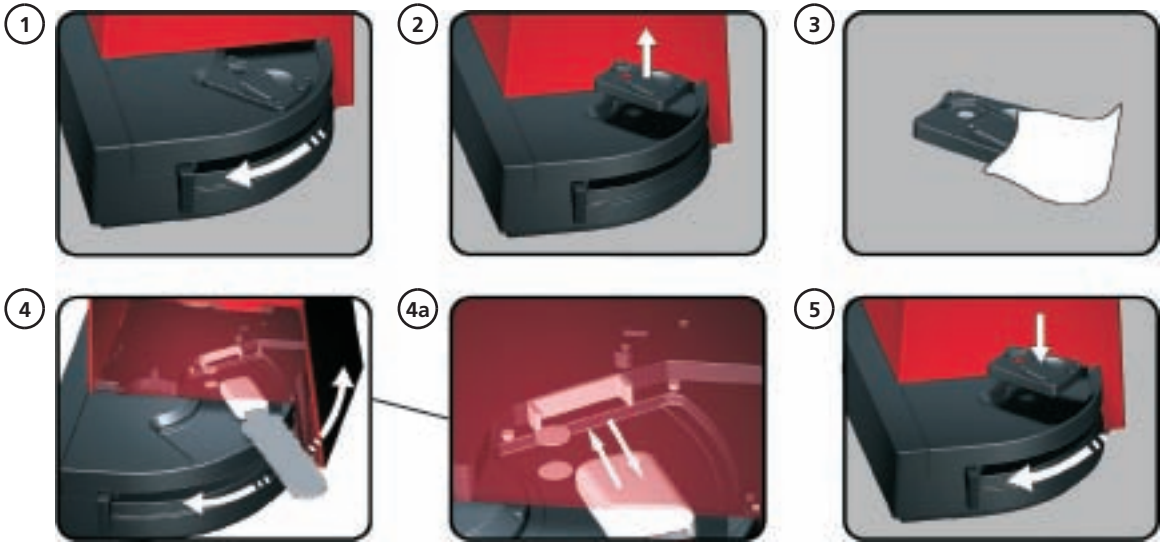
1. Sluit de kabel* aan op de analyser en de ASCII-printer* voordat u de test uitvoert.
2. Voer de meting uit.
3. Wanneer het resultaat op het display wordt getoond, drukt de printer het resultaat automatisch af.

* Niet inbegrepen.

De volgende instellingen van de COM-poort worden gebruikt.

Baud-rate	9600
Databits	8
Pariteit	Geen
Stopbits	1
Flowcontrol	Geen

Maintenance
Wartung
Maintenance
Onderhoud



GB/US

Before performing maintenance, make sure that the analyzer is turned off and that the display is blank.

1. The cuvette holder should be cleaned after each day of use. Pull the cuvette moving arm to its loading position.
2. Remove the cuvette holder by lifting it straight up.
3. Clean the cuvette holder with alcohol (20–70 %) or mild detergent. NOTE: The cuvette holder cannot be autoclaved.
4. If the optical parts becomes dirty, an error code will be displayed. To clean the optical parts, push a HemoCue Cleaner* into the opening of the cuvette holder. Move from side to side 5–10 times. If the cleaner is stained, repeat with a new cleaner. Make sure that the cleaner reaches the parts according to 4a.
5. Wait 15 minutes before replacing the cuvette holder. Make sure that the cuvette moving arm is in its loading position before replacing the cuvette holder. The cover may be cleaned with alcohol (20–70 %) or a mild detergent.

* One HemoCue Cleaner is included with the Analyzer. Contact your local distributor to order more.

DE

Überprüfen Sie vor der Durchführung von Wartungsarbeiten ob der Analyzer ausgeschaltet ist. Das Display darf nichts anzeigen.

1. Der Küvettenhalter sollte täglich nach Gebrauch gereinigt werden. Ziehen Sie den beweglichen Küvettenarm in seine Ladeposition.
2. Entfernen Sie den Küvettenhalter, indem Sie ihn gerade herausheben.
3. Reinigen Sie den Küvettenhalter mit Alkohol (20–70 %) oder einem milden Reinigungsmittel. HINWEIS: Der Küvettenhalter kann nicht autoklaviert werden.
4. Wenn die optischen Teile verschmutzt sind, wird ein Fehlercode angezeigt. Um die optischen Teile zu reinigen, schieben Sie einen HemoCue Cleaner* in die Öffnung des Küvettenhalters. Bewegen Sie ihn 5–10 Mal heraus und wieder hinein. Sollte der Reiniger verschmutzt sein, wiederholen Sie das Verfahren mit einem neuen Reiniger. Vergewissern Sie sich, dass der Reiniger die Teile gemäß 4a erreicht.
5. Warten Sie 15 Minuten, bevor Sie den Küvettenhalter wieder einsetzen. Vergewissern Sie sich, dass sich der bewegliche Küvettenarm in seiner Ladeposition befindet, bevor Sie den Küvettenhalter wieder einsetzen. Die Oberfläche kann mit Alkohol (20–70 %) oder einem milden Reinigungsmittel gereinigt werden.

* Ein HemoCue Cleaner ist im Lieferumfang des Analyzers enthalten. Um weitere Reiniger zu bestellen, wenden Sie sich bitte an Ihren Vertriebshändler vor Ort.

FR

Vérifier, avant la maintenance, que l'analyseur est éteint et que rien n'apparaît sur l'écran.

1. Le support de cuvette doit être nettoyé après chaque jour d'utilisation. Tirer le bras mobile de la cuvette vers sa position de charge.
2. Retirer le support de cuvette en le soulevant sans l'incliner.
3. Nettoyer le support de cuvette avec de l'alcool (20–70 %) ou un détergent doux. REMARQUE : Le support de cuvette ne passe pas à l'autoclave.
4. Si des pièces optiques se salissent, un code d'erreur s'affiche. Pour les nettoyer, introduire un tampon HemoCue Cleaner* dans l'ouverture du support de cuvette. Répéter l'opération de 5 à 10 fois. Si le tampon est taché, recommencer l'opération avec un nouveau tampon. Le tampon doit bien atteindre les pièces, comme indiqué dans l'image 4a.
5. Attendre 15 minutes avant de remettre le support de cuvette en place. Vérifier que le bras mobile de la cuvette se trouve en position de charge avant de remplacer le support de la cuvette. L'extérieur peut être nettoyé avec de l'alcool (20–70 %) ou un détergent doux.

* Un tampon HemoCue Cleaner est fourni avec l'analyseur. Contacter le distributeur local pour en commander.

NL

Controleer, voorafgaand aan het onderhoud, of de analyser uitgeschakeld is en het display niets weergeeft.

1. De cuvettehouder dient dagelijks na gebruik te worden gereinigd. Trek de cuvettehouder naar de laadpositie.
2. Til de cuvettehouder recht omhoog om deze te verwijderen.
3. Reinig de cuvettehouder met alcohol (20–70 %) of een mild reinigingsmiddel. OPMERKING: De cuvettehouder kan niet in de autoclaaf worden gesteriliseerd.
4. Als het optische gedeelte vuil wordt, wordt een foutmelding weergegeven. Om het optische gedeelte schoon te maken, duwt u een HemoCue Cleaner* in de opening van de cuvettehouder. Beweeg de cleaner 5–10 keer heen en weer. Als de cleaner vuil is, deze procedure met een nieuwe cleaner herhalen. Zorg ervoor dat de cleaner tot aan het gedeelte komt dat in afbeelding 4a wordt weergegeven.
5. Wacht 15 minuten voordat u de cuvettehouder terugplaatst. Zorg ervoor dat de cuvettehouder zich in de laadpositie bevindt voordat u de cuvettehouder terugplaatst. Het deksel kan worden schoongemaakt met alcohol (20–70 %) of een mild reinigingsmiddel.

* Eén HemoCue Cleaner wordt met de analyser meegeleverd. Neem contact op met uw leverancier om nieuwe exemplaren te bestellen.

GB/US Troubleshooting Guide

If you are unable to resolve the problem by following this Troubleshooting Guide, please contact your local HemoCue distributor or HemoCue AB. The Analyzer should be cleaned as described in the Maintenance section prior to service or disposal. Consult local environmental authorities for proper disposal. The Analyzer has no serviceable parts. NOTE! Do not open the cover of the Analyzer.

Symptom	Explanation	Action
Err01	A portion of the image area is unable to be analyzed. 1. Due to measurement error. 2. Due to abnormal sample.	1. Take a new microcuvette and repeat the measurement, as described in the Measuring section. 2. NOTE! The blood sample should be verified with a suitable laboratory method and be questioned as to the pathological condition of the patient.
Err02	Uneven spatial distribution of detected cells.	Take a new microcuvette and repeat the measurement, as described in the Measuring section.
Err03	Image, or part of the image area is detected as out-of-focus.	Take a new microcuvette and repeat the measurement, as described in the Measuring section.
Err30	1. Optical parts dirty. 2. Optical parts wet after cleaning.	1a. Turn off the analyzer and clean the optical parts as described in the Maintenance section. 1b. If the problem continues, the analyzer needs service. Contact your local distributor. 2. Wait 15 minutes before turning on the analyzer after cleaning to make sure that the optical parts are dry.
Err33	Empty microcuvette, not filled with sample.	Take a new microcuvette and repeat the measurement, as described in the Measuring section and make sure that the microcuvette is filled with sample.
Err34	Stray light detected.	a. Turn off the analyzer and make sure the analyzer is not exposed to any bright light sources. b. If the problem continues, the analyzer needs service. Contact your local distributor.
Err35	The battery power is too low.	Turn off the analyzer. a. Replace the batteries, six type AA, as described in the Start Up section. b. Use the power adapter as described in the Start Up section.

Symptom	Explanation	Action
Err60	General hardware error.	a. Turn off the analyzer and turn it on again after 30 seconds. Take a new microcuvette and repeat the measurement, as described in the Measuring section. b. If the problem continues, the analyzer needs service. Contact your local distributor.
Err61	Self test error during start up of analyzer.	a. Turn off the analyzer and turn it on again after 30 seconds. Take a microcuvette and perform the measurement, as described in the Measuring section. b. If the problem continues, the analyzer needs service. Contact your local distributor.
Err62	Blanking test failed for other reasons than Err30, Err34.	a. Turn off the analyzer and turn it on again after 30 seconds. Take a new microcuvette and repeat the measurement, as described in the Measuring section. b. If the problem continues, the analyzer needs service. Contact your local distributor.
WbC	Empty cuvette holder.	Take a microcuvette and perform the measurement, as described in the Measuring section.
LLL	1. Measured value is below 0.3 $x10^9$/L (300/mm^3, 300/µL). 2. Empty microcuvette, not filled with sample.	1. NOTE! Results exceeding the LLL limit should be verified with a suitable laboratory method and be questioned as to the pathological condition of the patient. 2. Take a new microcuvette and repeat the measurement, as described in the Measuring section and make sure that the microcuvette is filled with sample.
HHH	Measured value exceeds 30.0 $x10^9$/L (30000/mm^3, 30000/µL).	NOTE! Results exceeding the HHH limit should be verified with a suitable laboratory method and be questioned as to the pathological condition of the patient.

Symptom	Explanation	Action
No characters on the display.	1. Power is not received. 2. If on battery power, the batteries need to be replaced. 3. The display is out of order.	1a. Check that the power adapter is properly connected to the analyzer and the AC power supply, as described in the Start Up section. 1b. Check that the cable is not damaged. 2. Replace the batteries, six type AA, as described in the Start Up section. 3. The analyzer needs service. Contact your local distributor.
The display gives erroneous characters.	1. The display is out of order. 2. The microprocessor is out of order.	1, 2. The analyzer needs service. Contact your local distributor.
The display shows "FIR".	General analyzer software error.	a. Remove and replace all cables and/or batteries, and restart, as described in the Start Up section. b. The analyzer needs service. Contact your local distributor.
The display shows "  ".	1. The batteries need to be replaced. 2. If on AC power, the power adapter or the circuit board is out of order.	1. Turn off the analyzer and replace the batteries, six type AA, as described in the Start Up section. 2a. Check that the correct power adapter is used and properly connected and working, as described in the Start Up section. 2b. The analyzer needs service. Contact your local distributor.
The display does not switch from "  "and "WbC" to three flashing dashes and "  " (ready for measuring).	The cuvette holder sensor is out of order.	The analyzer needs service. Contact your local distributor.
The cuvette holder is not moving into the correct position.	The magnet in the cuvette holder is missing.	The analyzer needs service. Contact your local distributor.
Measurement on patient samples are higher or lower than antipicipated.	1. Improper sampling technique. 2. The microcuvettes are beyond their expiration date, damaged or have been improperly stored.	1. Take a new microcuvette and repeat the measurement, as described in the Measuring section. 2. Check the expiration date and the storage conditions of the microcuvettes.

Symptom	Explanation	Action
Measurement on control materials are out of range, either too high or too low.	1. Improper sampling technique. 2. The microcuvettes are beyond their expiration date, damaged or have been improperly stored. 3. The control material is beyond its expiration date or has been improperly stored. 4. The control material has not been mixed properly and/or is not at room temperature. 5. The control material is not suitable for use with the HemoCue WBC system.	1. Take a new microcuvette and repeat the measurement, as described in the Measuring section. 2. Check the expiration date and the storage conditions of the microcuvettes. 3. Check the expiration date and the storage conditions of the control material. If the problem continues, contact the manufacturer of the control material. 4. Make sure that the control material is mixed properly and at room temperature. If the problem continues, contact the manufacturer of the control material. 5. Contact your local distributor for control material information.

GB/US

Specifications

Intended Purpose/Intended Use
The HemoCue WBC system is indicated for use for quantitative determination of white blood cell (WBC) count in capillary or venous whole blood. The HemoCue WBC system is for *In Vitro* Diagnostic use only. The HemoCue WBC Analyzer is only to be used with HemoCue WBC Microcuvettes. The HemoCue WBC system is indicated for use in clinical laboratories and for point-of-care settings.

IVD Medical Device Directive
The HemoCue WBC system complies with the IVD Medical Device Directive 98/79/EC and carries the CE mark.

Principles of the Method/Procedure
Principle of the method
A hemolyzing agent lyses the red cells in the microcuvette and a staining agent colors the white cells. An image is taken of the stained white cells and the number of cells is counted by image analysis in the analyzer.
Principle of the procedure
The microcuvette serves as a sample container and reaction chamber. The microcuvette is for single-use only. A blood sample of approximately 10 µL is drawn into the cavity by capillary action. The microcuvette is placed in the analyzer. The result is obtained within 3 minutes. The system was designed and developed to establish agreement with the manual light microscopy method for white blood cell count. The system is factory calibrated and needs no further calibration.

Warning and Precaution
The microcuvettes are for *In Vitro* Diagnostic use only. Always handle blood specimens with care as they may be infectious. Consult local environment authorities for proper disposal. Always wear protective gloves when handling blood specimens. The microcuvettes are for single-use only.

Storage and Handling
HemoCue WBC Microcuvettes
The Microcuvettes are to be stored at 15–35 °C (59–95 °F), <90 % non-condensing humidity. Once the seal of the vial is broken, the microcuvettes are stable for 3 months. An unopened vial of microcuvettes can be stored for a shorter period of time (4 weeks) outside the specified storage conditions down to 0 °C (32 °F) and up to 50 °C (122 °F), <90 % non-condensing humidity. Allow the microcuvettes to reach 15–35 °C (59–95 °F) before use. Use the microcuvettes prior to the expiration date that is printed on the package. Keep the vial properly closed. All unused microcuvettes should remain in the original package.
HemoCue WBC Analyzer
The analyzer can be stored in temperatures between 0–50 °C (32–122 °F), <90 % non-condensing humidity. Operating temperature is 15–35 °C (59–95 °F), <90 % non-condensing humidity. Allow the analyzer to reach ambient temperature before use.

Specimen Collection and Preparation
Capillary or venous whole blood may be used. EDTA anticoagulant may be used, preferably in solid form to avoid dilutional effects. Mix all specimen tubes thoroughly on a mechanical mixer for at least 2 minutes or invert the tube 10–20 times by hand. The specimen can be stored at room temperature (15–35 °C, 59–95 °F), or in a refrigerator (2–8 °C, 35–46 °F) for 48 hours. If the specimen has been stored in a refrigerator, it will be viscous and the blood should be allowed to warm up to room temperature before mixing.

Materials Required
- HemoCue WBC Analyzer
- HemoCue WBC Microcuvettes
- Lancet (capillary samples)

• Pipette or other transfer device (venous samples)
• Lint-free tissue (non-fraying)

Quality Control
The HemoCue WBC Analyzer has an internal quality control, the "self test". Every time the analyzer is turned on, it will automatically verify the measurement performance. When passing the self test, the display will show the HemoCue symbol and three flashing dashes, indicating that the analyzer is ready to perform a measurement. An error code will be displayed if the self test fails. Another part of the built in self test (QC) is performed for each measurement, including both checks of the HemoCue WBC Analyzer but also several condition checks of the HemoCue WBC Microcuvette and the sample itself. The operator's ability to handle the microcuvette and apply the sample correctly is also included in these self tests. No additional quality controls performed by the operator are required for verification of the system functionality. Note that local, state, or other accreditation agencies may require additional quality control testing. If additional quality control checks are required, R&D Systems R&D HC WBC Control may be used. Please refer to the R&D HC WBC Control, as well as the HemoCue WBC Operating Manual regarding handling and procedures.Please refer to local guidelines for recommended frequency of use.

Expected Values (Dacie and Lewis Practical Haematology)
Adults 4.0–10.0 x10^9/L
Children 1 year 6.0–16.0 x10^9/L
Children 2–6 years 5.0–15.0 x10^9/L
Children 6–12 years 5.0–13.0 x10^9/L
Infants 1 month 5.0–19.0 x10^9/L
Infants 2 months 5.0–15.0 x10^9/L
Infants 3–6 months 6.0–18.0 x10^9/L

The values above may vary due to a wide range of factors, such as sex, diurnal variations, exercise, physical stress or trauma, pregnancy, indigestion of food, and cigarette smoking.

Measuring Range
Displayed range: 0.3–30.0 x10^9/L (300–30000/mm^3, 300–30000/µL). Results above the measuring range will be displayed as HHH. Results below the measuring range will be displayed as LLL.

Limit of Detection
Functional Sensitivity is estimated as the mean concentration for a spiked sample whose CV is 20 %. The Functional Sensitivity has been determined to be 0.3 x10^9/L. (James O. Westgaard, Basic Method Validation)
Limit of Blank is defined as the highest measurement result that indicates that the analyte is not present in the sample. Limit of Blank has been determined to be 0.06 x10^9/L (CLSI Document EP17-A).

Limitations of the Method/Procedure
a) The measurement should be made as soon as possible, but within 40 seconds after the blood has been drawn into the microcuvette.
b) Do not remeasure the filled microcuvette.
c) Mixing samples for an extended period may affect the result.
d) Results above the measuring range will be displayed as HHH. Results below the measuring range will be displayed as LLL.
e) Studies have shown that patient samples with >2 % nucleated red blood cells (NRBCs) may give falsely elevated white blood cell count.

Specific Performance Characteristics

Linearity

The method used in the HemoCue WBC system has according to the CLSI Document EP06-A been demonstrated to be linear between 0.3–30.0 $x10^9$/L (300–30000/mm^3, 300–30000/µL), within 0.2 $x10^9$/L difference in 0.3–3.5 $x10^9$/L and within 6 % difference in 3.6–30.0 $x10^9$/L.

Within-run and Total Precision

Within-run and Total Precision was determined according to the CLSI Document EP05-A2. The results given below come from four batches of HemoCue WBC Microcuvettes, and five HemoCue WBC Analyzers. Commercially available controls at three different levels were used. The WBC count was measured in duplicate twice a day, morning and afternoon, during 20 consecutive days.

Level	N	$x10^9$/L	Within-run Precision CV %	Total Precision CV %
1	400	2.5	4.06	5.4
2	400	7.2	2.92	3.5
3	400	19.0	1.63	1.9

Additionally, a study has been performed to determine the precision using fresh blood samples. The study was performed on venous whole blood samples tested in duplicate.

$x10^9$/L	N	$CV_{duplicates}$ %	
		Sysmex XS-1000i	HemoCue WBC
0.3–1.0	12	5.0	10.4
1.1–3.5	52	3.7	4.1
3.6–10.0	209	1.9	3.5
10.1–20.0	88	2.1	2.5
20.1–30.0	35	1.8	2.2
Total	396	2.4	3.2

Validation Studies

Results of the validation studies, based on the intended use of the system, are shown in Figure 1, 2, 3 and 4. Single replicate on the HemoCue WBC system and the mean of duplicate on the comparative method are presented in the plots.

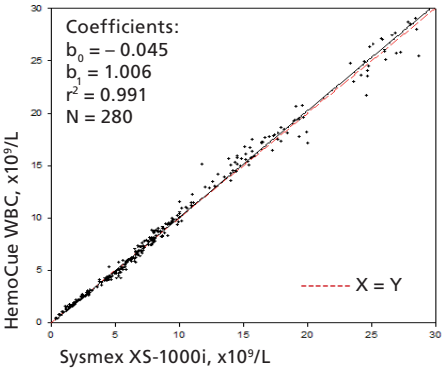


Figure 1
Point-of-Care

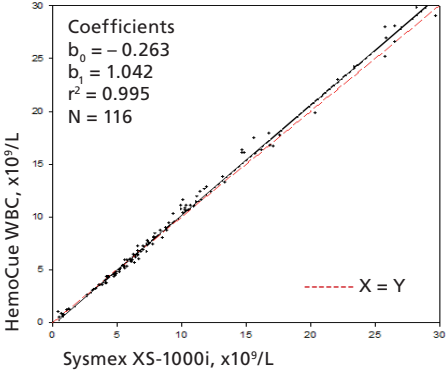


Figure 2
Clinical Laboratory

When a capillary skin puncture is performed, several defense systems in the body are activated very quickly. These defense systems cause an increase in the number of WBCs in the blood closest to the wound, leading to greater differences in results from several samples taken from the same finger stick.

A study was performed, on the HemoCue WBC system in which possible influences of capillary sampling technique were included, see Figure 3 below.

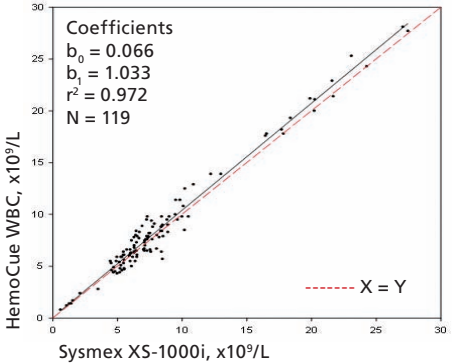


Figure 3
Capillary Sampling Technique

An additional study has been performed at a clinical reference laboratory in the U.S. including a large number of blood samples in order to evaluate the HemoCue WBC system for expected demographic variations (age, gender, geographics) in the population, see Figure 4 below.

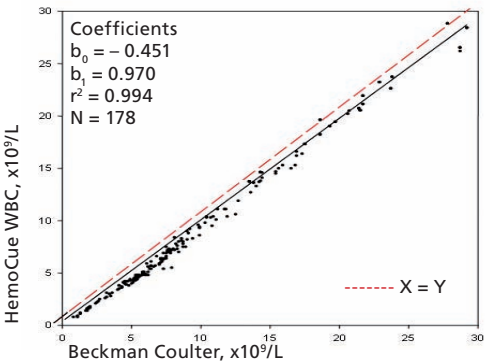


Figure 4
Demographic Sample Population

Interference Studies

Interference studies were performed according to CLSI Document EP07. The following substances have not been found to interfere with the HemoCue WBC system. The highest concentration or percentages tested is referred to in brackets.

Acetaminophen (20 mg/dL), ascorbic acid (6 mg/dL), ibuprofen (50 mg/dL), caffeine (308 µmol/L), creatinine/urea (30 mg/dL/500 mg/dL), salicylic acid (60 mg/dL), tetracycline (30 mg/dL), unconjugated bilirubin (342 µmol/L), conjugated bilirubin (380 µmol/L), dextran 40 (30 g/L), osmolality (167 mmol/L), HbCO (30 %), methemoglobin (50 %), thrombocytes (2000 $x10^9$ g/L), lipemia (intralipid 3100 mg/L) which corresponds to triglycerides (approximately 10.5 mmol/L), hemoglobin (30–250 g/L), reticylocytes (258 $x10^9$ L), HbAS, immature leukocytes and platelet clumping have not been found to interfere. pH values between 6.8–8.0 do not interfere with the system.

Technical Specifications

Dimensions: 185 x 133 x 120 mm (7.28 x 5.24 x 4.72 inches)
Weight: 600 g (1.32 pounds) (with 6 AA batteries installed)
Power adapter: CE marked
Only use adapters, as listed under Adapters.
Pollution degree: 2
Overvoltage category: II
Atmospheric pressure: 700 hPa to 1060 hPa.

Equipment not suitable for use in the presence of flammable mixtures.

The HemoCue WBC system has been tested for electrical safety and EMC according to the following standards:

- EN 60601-1:1990, A1:1993, A2:1995, A13:1996 Medical electrical equipment – Part 1: General requirements for Safety.
- EN 60601-1-1:2001 Medical electrical equipment – Part 1-1: General requirements for Safety – Collateral Standard: Safety requirements for medical electrical systems.
- UL 60601:2003 Medical electrical equipment – Part 1-1 General requirements for Safety.
- EN 61010-2-101:2002 Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-101: Particular requirements for *in vitro* diagnostic (IVD) medical equipment.
- UL 61010-1:2004 Safety requirements for electrical equipment for measurement, control and laboratory use – Part 1: General requirements.
- IEC/EN 60601-1-2+A1 Medical electrical equipment-Part 1: General requirements for Safety – Part 1-2: Collateral Standard: Electromagnetic compability – requirements and tests.

Recommended separation distance between Portable and mobile RF communications equipment and HemoCue WBC Analyzer

The HemoCue systems are intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of HemoCue systems can help prevent electromagnetic interference by maintaining a minimum distance between portable and RF communications equipment (transmitters) and HemoCue systems as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d=1.2\sqrt{P}$	80 MHz to 800 MHz $d=1.2\sqrt{P}$	800 MHz to 2.5 GHz $d=2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at maximum output power not listed above, the recommended separation distances (d) in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where (P) is the maximum output power rating of the transmitter in watts (W) according to transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequencyrange applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Guidance and manufacturer's declaration – Electromagnetic immunity
The HemoCue systems are intended for use in the electromagnetic environment specified below. The customer or user of the HemoCue systems should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/ burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	2 kV for power supply lines ±1 kV for input/ output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode	±1 kV differential mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply lines IEC 61000-4-11	<5 %U (>95 % dip in U) for a 0.5 cycle 40 %U (60 % dip in U) for 5 cycles 70 %U (30 % dip in U) for 25 cycles <5 %U (>95 % dip in U) for 5 seconds For explanation of U see NOTE 1	<5 %U (>95 % dip in U) for a 0.5 cycle 40 %U (60 % dip in U) for 5 cycles 70 %U (30 % dip in U) for 25 cycles <5 %U (>95 % dip in U) for 5 seconds	Mains power quality should be that of a typical commercial or hospital environment. If the user of the HemoCue systems image intensifier requires continued operation during power mains interruptions, it is recommended that the HemoCue systems image intensifier be powered from an uninterruptible power supply or a battery.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz See NOTE 2 and NOTE 3	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the HemoCue systems, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter Recommended separation distance $d=1.2\sqrt{P}$ $d=1.2\sqrt{P}$ 80 MHz to 800 MHz $d=2.3\sqrt{P}$ 800 MHz to 2.5 GHz Where (P) is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and (d) is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey (a), should be less than the compliance level in each frequency range (b). Interference may occur in the vicinity of equipment marked with the following symbol. 

NOTE 1 U is the a.c. mains voltage prior to application of the test level.

NOTE 2 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 3 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, MA and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the HemoCue systems are used exceeds the applicable RF compliance level above, the HemoCue systems should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the systems.
b) Over the frequency range 150 KHz to 80 Mhz, field strength should be less than 3 V/m.

Technical specifications (EMC-RF)

Use only cables with the following specification:

USB shielded maximum 2 m

Serial shielded maximun 1.5 m

Guidance and manufacturer´s declaration – electromagnetic emissions The HemoCue systems are intended for use in the electromagnetic environment specified below. The customer or the user of the HemoCue systems should assure that it is used in such an environment.		
Emission test	Compliance	Electromagnetic environment – guidance
RF emissions	Group 1	The HemoCue systems uses RF energy only for its internal function. Therefore, its RF emissions are very low and not likely to cause any interference in nearby electronic equipment
RF emissions	Class B	The HemoCue systems are suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Adapters
Country: EU/US/GB
Type: FW7333SM/12
Input: 100V~ – 240 V~, 50–60 Hz, 200 mA

Country: EU/US/GB
Type: HCA01
Input: 100 V~ – 240 V~/50–60 Hz/<500 mA

Warning
The device is tested according to standard IEC/EN 60601-1-2 and is found to comply with the standard.
Despite this compliance it is impossible to predict any possible effects by other nearby standing instruments, (stationary, portable or mobile units) or the possible impact of electromagnetic radiance. This is the reason we need to inform users of this Analyzer that disturbance from other equipment might affect the performance of the Analyzer. Should you note that this is the fact, please contact your local HemoCue distributor.
The HemoCue WBC is intended for use in the electromagnetic environment specified in Technical specifications. The customer or user of the HemoCue WBC system should assure that it is used in such an environment. The HemoCue WBC Analyzer uses RF energy only for its internal function. Therefore, its RF emissions are very low and not likely to cause any interference in nearby electronic equipment.
The HemoCue WBC system is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Accessory equipment connected to the analog and digital interfaces must be certified according to the respective IEC standards (i.e. IEC 60950-1 for data processing equipment and IEC 60601-1 for medical equipment).
Furthermore all configurations must comply with the system standard, IEC 60601-1-1. Connections of additional equipment to the signal input or signal output connections is deemed to be "configuring a medical system", and therefore assumes responsiblity for the systems compliance within the requirements of IEC 60601-1-1. For further information, please contact your local distributor.

Warranty
The Analyzer carries a 24-month warranty from the day of receipt. After the expiration date of the warranty, service such as maintenance and repairs are offered at a fixed price.

Service and Disposal
The Analyzer should be cleaned as recommended under Maintenance prior to service or disposal. Consult local environmental authorities for proper disposal.

Spare Parts and Accessories
The following accessories and spare parts are available:
- Power adapter
- Cuvette holder
- HemoCue Cleaners
- HemoCue Lancets

Patents
The product is protected by the following patents (or Patent Pending):
SE 0 500 549, US 5 674 457
EP 0 821 784, SE 0 601 576
US 552 500, RCD 00563838
US 11/102 837, EP 06110903.9
US 11/717 675, PCT SE2007/000654
US 60/906 504

Symbols Used


Attention, see instructions for use


CE mark


Class II equipment


Only valid within the European Community. Indicates seperate collection for waste of electrical and electronic equipment.

Serial port

Relative humidity, non-condensing

Temperature

Efficiency Level

References

1. HemoCue WBC Microcuvettes package insert.
2. Dacie and Lewis, Practical Haematology Tenth edition.
3. Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline CLSI Document EP05-A2.
4. Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline CLSI Document EP06-A.
5. Interference Testing in Clinical Chemistry; Approved Guideline CLSI Document EP07-A2.
6. Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline Document CLSI EP09-A2.
7. Protocols for Determination of Limit of Detectionand Limit of Quantification; Approved Guideline CLSI Document EP17-A
8. James O. Westgard, Basic Method Validation.

Manufacturer

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