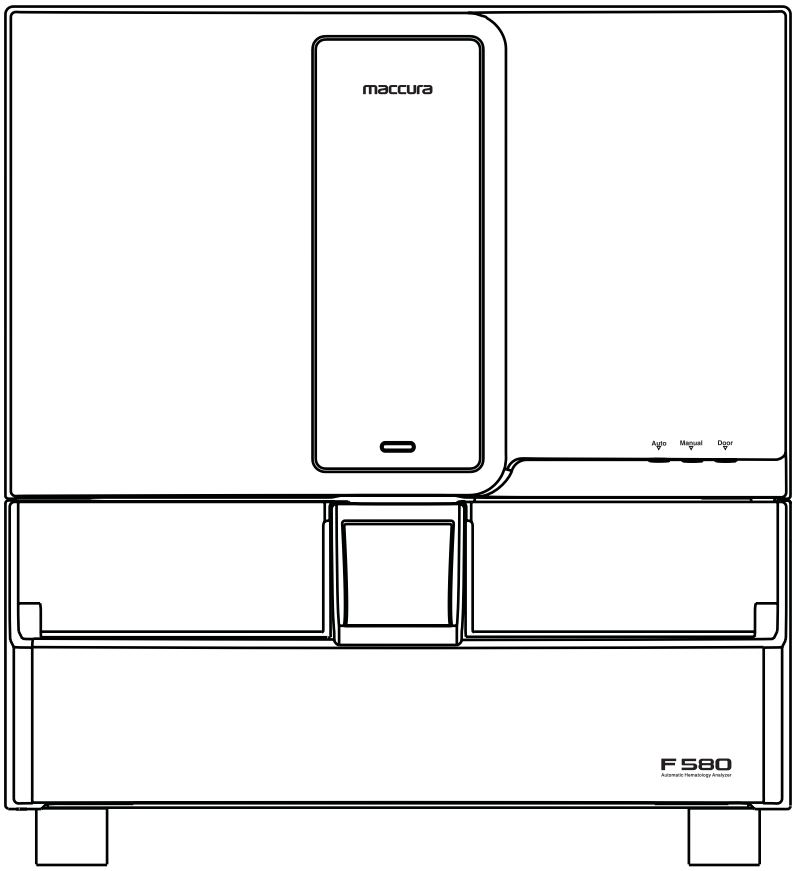
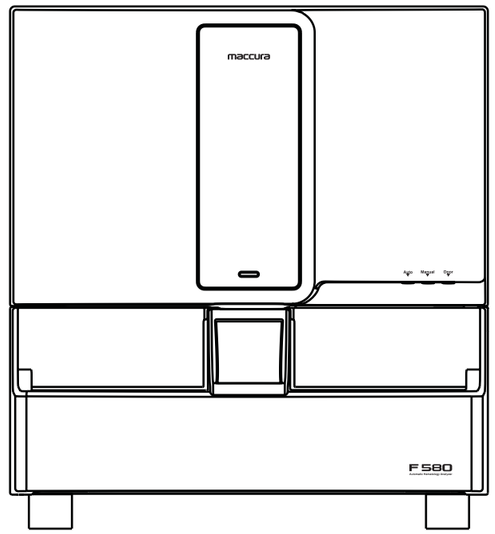
maccura

Otomatik Hematoloji Analizörü





Otomatik Hematoloji Analiz Cihazı Kullanım Kılavuzu

Kılavuzu okuyun ve kaynaklayın
■ Lütfen kullanmadan önce güvenlik kılavuzunu dikkatlice okuyun ve doğru bir şekilde anlayın.
■ Lütfen kılavuzu ileride başvurmak üzere kolay erişebileceğiniz bir yerde saklayın.

Üretici: Maccura Medical Instrument Co., Ltd.

Revizyon Geçmişi

Manuel Sürüm	Tarih
İlk Sürüm	

SİSTEM VERSİYONU TELİF HAKKI

1. Bu kılavuzda yer alan veriler önceden haber verilmeksizin değiştirilebilir.

2. Bu kılavuzun telif hakkı Maccura Medical Instrument Co., Ltd.'ye aittir.
   Maccura Medical Instrument Co., Ltd.'nin önceden yazılı izni olmaksızın bu kılavuzdaki hiçbir bilgi hiçbir koşulda çoğaltılamaz, yeniden basılamaz veya üçüncü bir tarafa ifşa edilemez.

3. Maccura Medical Instrument Co., Ltd., bu kılavuzda açıklanmayan kullanımdan veya kullanımdan sonra doğrudan veya dolaylı olarak ortaya çıkan herhangi bir hasardan sorumlu olmayacaktır.

4. Kullanıcılar cihazı kılavuzda yer alan düzenlenmiş yöntemlere göre kullanmazlarsa cihaz tarafından sağlanan koruma bozulabilir.

İçerik Tablosu

Giriş

Maccura Medical Instrument Co., Ltd.'nin (bundan böyle "Şirket" olarak anılacaktır) Otomatik Hematoloji Analizörünü (bundan böyle "Analizör" olarak anılacaktır) satın aldığınız için teşekkür ederiz.

- Lütfen analizörü profesyonel eğitim almış teknisyenlerin gözetiminde kullanın. Klinik muayene için kullanıldığında lütfen doktorların veya klinik laboratuvar teknisyenlerinin gözetiminde kullanın.

- Reaktiflerin veya sarf malzemelerinin yanlış kullanılması durumunda yanlış sonuç verebilir ve hatta analizör veya operatöre zarar verebilir.
- Cihazın doğru çalışması için lütfen kullanmadan önce kullanım kılavuzunu baştan sona okuyun.

- Lütfen kılavuzu ileride başvurmak üzere kolay erişebileceğiniz bir yerde saklayın.

Kılavuzun İçeriği

Bu kılavuz 12 bölüm ve 1 ek içermektedir. Lütfen gerektiği gibi uygun bölümü bulun.

Bölüm	**Bölüm İçeriği**
Bölüm 1 Kılavuza genel bakış	Analizör kılavuzunu özetler
Bölüm 2 Sistem Girişi	■ Analizörün kullanım amacını ve ölçüm parametresini tanıtır ■ Analizörün oluşturma ve çalıştırma arayüzünü tanıtır
Bölüm 3 Tasarım ilkesi	■ Analizörün tasarım prensibini ve çalışma sürecini tanıtır
Bölüm 4 Sistem Kurulumu	■ Analizörün kurulum gereksinimlerini ve yöntemini tanıtır
Bölüm 5 Temel Ayar	■ Analizörün referans aralığını ve diğer sistem ayarlarını tanıtır
Bölüm 6 Rutin çalışma	■ Numune toplama, hazırlama ve analiz sürecini tanıtır ■ Analizörün rutin çalışmasını tamamlama
Bölüm 7 Çalışma	■ Çalışma arayüzünde numune girişi, sonuç görünümü ve diğer işlemler
Bölüm 8 Sonuç Görünümü	■ Analizörün numune analiz sonuçlarını görüntüleme
Bölüm 9 Analizör Kalibrasyonu	■ Analiz cihazının kalibrasyon gereksinimlerini ve yöntemini tanıtır
Chapter 10 Kalite Kontrol	■ Kalite gerekliliklerini ve analizör yöntemini tanıtır
Chapter 11 Bakım	■ Analizörün bakım yöntemini tanıtır
Bölüm 12 Sorun Giderme	■ Analizörün arıza nedenini ve işleme yöntemini tanıtır
Ek	■ Analizörün özelliklerini tanıtır

Ürün Garantisi

Kullanıcı kılavuzundaki sınırlı içerik nedeniyle, Otomatik Hematoloji Analizörünün normal kullanımını sağlamak için lütfen kullanım kılavuzunda kayıtlı yöntemlere bakın.

a. Garanti Aralığı

Cihaz, üretim hatası nedeniyle arızalanırsa ücretsiz olarak onarılacaktır. Ancak onarım durumunda, bazen öğe değiştirilir.

b. Garanti Bölgesi

Satış yapılan ülke içinde

c. Sorumluluk Reddi

Aşağıdaki durumlarda garanti süresi içinde dahi garanti geçerli değildir:

- Yanlış kurulum koşullarında kullanım nedeniyle arıza.
- Kılavuzda belirtilmeyen güç kaynağı, voltaj veya frekanstan veya anormal güç kaynağından kaynaklanan arıza.
- Havadaki güçlü aşındırıcı gaz nedeniyle devre korozyonu ve bozulmasından kaynaklanan arıza.
- Şirket tarafından sağlanmayan donanım, yazılım veya aksesuarların kullanımından kaynaklanan arızalar.
- Yanlış uygulama yöntemi veya kılavuzda kayıtlı olmayan uygulama yönteminden kaynaklanan arızalar veya maccura tarafından yapılmayan bakım nedeniyle arızalar.

- Maccura tarafından belirlenmemiş şirketler tarafından bakım nedeniyle oluşan arızalar.
- Maccura tarafından onaylanmayan hareket veya nakliye nedeniyle arıza.
- Müşteri tarafından sökme veya değiştirmeden kaynaklanan arıza.
- Yangın, deprem, rüzgar, sel, gök gürültüsü, suç, şiddet, terörist, radyoaktif kirlenme, uyarma, tehlikeli madde ve diğer karşı konulmaz doğal tehlikelerden kaynaklanan arızalar.
- Eski veya Maccura'nın yazılı izni olmadan yeniden satın alınan enstrümanda meydana gelen arızalar.

d. Kullanım kılavuzu üzerindeki haklar

Bu kullanım kılavuzu önceden haber verilmeksizin değiştirilebilir.

Kurulum, taşıma ve satış sonrası servis

a. Kurulum ve taşıma

Kurulum sırasında, kullanıcının kullanım kılavuzuna göre cihazın kurulumu için donanım koşullarını ve uygun çalışma ortamını hazırlaması gerekir.

b. Satış sonrası servis

- Satış sonrası servis ve bakım sözleşmesi ile ilgili olarak lütfen şirketin servis departmanı veya yetkili distribütörü ile iletişime geçin.
- Garanti süresinin ötesindeki servis konusunda şirket veya yetkili distribütörün servis departmanı ile görüşmek için lütfen bakım sözleşmesini, muayene servis sözleşmesini vb. getirin.

İmha etme

Cihazın atılması, ilgili ulusal mevzuata uyulmasını gerektirir

Nasıl yardım alınır

Otomatik Hematoloji Analizörü kurulumu ve kullanımı sırasında herhangi bir sorunla karşılaşırsanız ve yardıma ihtiyaç duyarsanız, lütfen aşağıdaki iletişim yöntemleri ile Maccura Medical Instrument Co., Ltd.'nin servis bölümü veya yetkili distribütör ile iletişime geçin:

- Şirket İnternet Adresi: www.maccura.com
- İletişim Bilgisi:
  Tel: +86 28 87854598 +86 28 87854582 Fax:
  +86 28 87831961
  E-posta：maccura@maccura.com

Lütfen aşağıdaki bilgileri hazırlayın:

- Otomatik Hematoloji Analizörünün üretim numarası (cihazın arka panelindeki isim levhasını kontrol edin)
- Sorunların tanımı
- Sorunu çözmek için kullandığınız yöntemler ve işlem adımları
- Cep telefonu numaranız, faksınız ve e-posta adresiniz vb. dahil olmak üzere iletişim bilgileriniz.

Kullanıcı Eğitimi

Firma, Otomatik Hematoloji Analizörünün çalıştırılması konusunda eğitim hizmeti verecektir. Detaylı bilgi için lütfen firmanın servis departmanına danışınız.

Üretim tarihi ve raf ömrü

Cihazın üretim tarihi isim plakasında yazılıdır, raf ömrü 5 yıldır.

Cihazın ve sıvı atıkların atılması

Cihazı atmadan önce, güvenlik prosedürleri hakkında tavsiye almak için lütfen servis departmanımızla iletişime geçin.
Lütfen cihazı yerel çevre koruma yönetmeliklerine göre atın.
Lütfen atıkları kesinlikle geçerli çevre koruma yönetmeliklerine göre atın.

Depolama ve nakliye

Depolama

Ambalajlı cihaz, aşındırıcı gazların olmadığı ve iyi havalandırılan bir ortamda saklanmalıdır ve sıcaklık -10℃～ 40℃, bağıl nem %10 ～ 90%.

Nakliye

Lütfen nakliye için şirketin belirlediği özel ambalaj kutusunu kullanın ve ambalajsız taşımayı yasaklayın.
Paketleme kutusu, paketleme talimatına göre araca sabitlenmeli, boşaltmayı ve çarpmayı yasaklamalıdır.
Neme ve güneş kremine dikkat edin ve nakliye sırasında yağmuru engelleyin.

Diğer önlemler

(1) Çevresel koşullar

Cihaz, aşağıdaki çevre koşulları karşılandığında kullanılmalıdır.

a. Temiz hava ve iyi havalandırın.
b. Doğrudan güneş ışığından kaçının.
c. Masa yatay durur (eğim 1/200 veya daha düşüktür)
d. Masa, enstrümanın ağırlığına dayanabilir.
e. Ortam sıcaklığı 15℃～ 30℃ aralığındadır, ölçüm yaparken hata ±2℃'dir.
f. Bağıl nem %30 ～ %85 aralığındadır ve cihazın yüzeyinde yoğuşma yoktur.

g. İnsan vücudunun hissedebileceği bir titreşim yoktur.
h. Cihazın 5 metre yakınında bir güç dağıtım panosu bulunmaktadır.
i. Voltaj dalgalanması ±%10 aralığındadır.
j. Elektromanyetik ve manyetik parazit oluşturabilecek cihazlardan (örn. santrifüj, EDM makinesi, telefon, telsiz ve telsiz telefon vb.) uzak tutunuz.

k. Bir toprak terminali var (topraklama direnci 10Ω veya daha düşük).
l. Enstrüman çalışırken gürültü 60db'den azdır (ara sıra gürültü dahil değildir).

m. Cihaz hazır durumdayken gürültü 45 db'den azdır.

(2) Disposal of reagent, sample and consumables

a. Lütfen biyolojik tehlikeler için ulusal güvenlik yönergelerinde veya düzenlemelerinde veya satışın yapıldığı ülkedeki ilgili çevre koruma düzenlemelerinde açıklanan önlemlere uyun.
b. Numunelerin belirtilen standartlara göre kullanılmasından sonra elden çıkarılması, muhafaza edilmesi veya terk edilmesinden kullanıcılar sorumludur. Bu nedenle, işlem hatası veya başka nedenlerle numunenin beklenmedik şekilde kaybolmasını önlemek için numunelerin bir kısmının önceden çıkarılması ve saklanması tavsiye edilir.

Önemli Güvenlik Bilgisi

Otomatik Hematoloji Analizörünü çalıştırmadan önce lütfen aşağıdaki uyarıları ve hatırlatmaları dikkatlice okuyunuz.

Cihaz üzerindeki uyarı işaretleri veya kılavuzdaki tehlike uyarıları, uyarı işaretleri ve tek kelimeden oluşan (tehlike, uyarı ve dikkat gibi) aşağıdaki uyarı başlıklarını içerir.

	Bir güvenlik uyarı sembolü. Bu kılavuzun ilgili güvenlik açıklamalarında tehlike uyarısı kelimesinden önce gelir. Lütfen bu sembolün arkasındaki tüm güvenlik bilgilerine dikkat edin.
	**Danger Tehlike:** Kaçınılmazsa birkaç yaralanmaya veya yaralanmaya neden olabilecek acil tehlikeli durumu belirtir.
	**Warning Uyarı:** Kaçınılmazsa birkaç yaralanmaya veya yaralanmaya neden olabilecek potansiyel tehlikeli durumu belirtir.
	**Caution Dikkat:** Kaçınılmazsa hafif veya orta dereceli ağrılara neden olabilecek potansiyel tehlikeli durumu belirtir.

	**Caution Dikkat:** Önlenemediği takdirde mal ve veri kaybına veya çevre kirliliğine neden olabilecek potansiyel tehlikeli durumu belirtir.

Bu kılavuzda tehlike kullanılmamıştır.

Yukarıda belirtilen uyarı ve hatırlatmalara ek olarak, bu kılavuzda ifade için aşağıdaki kelimeler kullanılacaktır.

Not: Herhangi bir arızayı önlemek için doğru test için ürünün doğru kullanımını sağlamak için kullanım talimatlarını gösterir.

Çalıştırmadan önce alınacak önlemler

Cihazın çalışması ve kullanım kılavuzu

Bulaşıcı maddelerden kaynaklanan kontaminasyonu önlemek için lütfen cihazı kullanmadan önce koruyucu giysiler giydiğinizden emin olun. Koruyucu giysiler bakım ve muayenede her zamankinden daha önemli. Belirli bir yönetmelik veya el kitabı varsa lütfen yönetmeliklere uyun.
Kullanım kılavuzunda belirtilenler dışında herhangi bir işlem yapmayınız. Cihazla ilgili herhangi bir sorun varsa lütfen şirketin servis departmanıyla iletişime geçin.
Lütfen cihazda veya kullanım kılavuzunda açıklanan önlemlere ve talimatlara uyduğunuzdan emin olun. Kullanıcılar cihazı kılavuzdaki düzenlemelere göre kullanmazlarsa cihaz bozulabilir.
Tüm kazalar tahmin edilebilir değildir, bu nedenle kılavuzdaki ve cihazdaki tehlikeli uyarı işaretleri tüm olası durumları kapsayamaz. Sadece verilen yönergeleri takip etmek yeterli değildir. Lütfen tetikte olun ve sağduyunuzu kullanın.

Cihaz Çalışması

Doğruluğun kontrolünü sağlamak için lütfen reaktif stabilitesi ve cihaz çalışması sırasında kontrolü test edin. Hasta numunesinin testinden önce, lütfen kontrolün test sonucunun gereksinimleri karşıladığından emin olun. Lütfen bazı reaktiflerin saklanması, bertarafı ve kullanım yöntemi ve kontrolü (ambalaj açmadan önce ve sonra) ile ilgili kullanım kılavuzunun gerekliliklerine uyun.

Diğer güvenlik önleyici tedbirler

Lütfen cihazda değişiklik yapmayın veya kılavuzda izin verilenler dışında bileşenleri kullanmayın, aksi takdirde tehlike oluşabilir.
Lütfen bakım için kullanılanlar dışında başka organik reaktifler kullanmaktan kaçının.

Kullanım için önlemler

Bu cihazı kullanırken lütfen anormal gürültüye, su sızıntısına ve diğer anormalliklere dikkat edin. Yukarıdaki sorunlar meydana gelirse, lütfen belirli koşullara göre uygun güvenlik önlemlerini alın ve şirketin servis departmanı ile iletişime geçin.
Lütfen çalışma sırasında cihazın üst kapak plakasını açmayın, aksi takdirde tehlike oluşabilir.

Kurulum ve bakım ile ilgili önlemler

Kullanıcıların cihazı bireysel olarak kurmalarına izin verilmez. Cihazın güvenliğini ve normal kullanımını sağlamak için şirketin servis departmanı kurulum hizmeti verecektir.
Kullanıcının bakımı altındaki testler bu kılavuzda açıklananlarla sınırlıdır. Lütfen bakımdan önce ayrıntıları anlayın. Lütfen kılavuzda açıklanmayan testleri sürdürmeye çalışmayın; aksi takdirde alet tehlikeye girecek ve kişisel yaralanma meydana gelebilir.
Uyarı işaretleri eskimiş veya hasarlı ise, değiştirilmesi için lütfen şirketin servis departmanı ile iletişime geçin.

Uyarı notları

Bu kılavuzdaki uyarı notları ve konumları aşağıda listelenmiştir.
Aşağıda belirtilen koruyucu cihazlar tıbbi eldivenler, koruyucu gözlükler, koruyucu bezler ve maskeyi içerir.

Uyarı bildirimleri Listesi

Sıvı atıkların neden olduğu enfeksiyon

- Sıvı atık ile temas enfeksiyona neden olabilir.
- Lütfen bakım ve incelemeden önce koruyucu cihazları takın.
- Sıvı atık cilde temas ederse, lütfen cildi hemen akan su ile yıkayın ve temas bölgesini dezenfekte edin. Gerekirse, lütfen tıbbi yardım alın.

Numunenin neden olduğu enfeksiyon

- Numune ile temas enfeksiyona neden olabilir.
- Numuneyi atarken lütfen koruyucu cihazları takın.
- Numune cilde temas ederse, lütfen cildi hemen akan suyla yıkayın ve temas bölgesini dezenfekte edin. Gerekirse, lütfen tıbbi tavsiye isteyin.

- Numune bir cihazın üzerine düşerse, lütfen koruyucu cihazı takın, solüsyonu silin ve temas bölgesini dezenfekte edin.

Cihaz birimleriyle temastan sonra oluşan enfeksiyon/hasar

- Örnekleme ünitesi, reaktif enjeksiyon ünitesi, temizleme ünitesi veya diğer ünitelerle temas enfeksiyona veya hasara neden olabilir.
- Bakım ve muayene sırasında lütfen koruyucu cihazı taktığınızdan ve kılavuzda açıklanan prosedürlere uyduğunuzdan emin olun.

- Lütfen bakımdan önce cihazın çalışmadığından emin olun.
- Numune rakı ve numune tepsisi ile temas yaralanmaya veya enfeksiyona neden olabilir.
- Cihaz çalışırken, yazılım tarafından örneklemenin durduğunu gösterdiğinde lütfen numuneyi yükleyin veya boşaltın. Numuneyi yüklemeden veya boşaltmadan önce lütfen numune tepsisini güvenli konuma çevirin.
- Numune kolunda ve numune tepsisinde bir alarm varsa, numune alma dursa bile numuneyi yüklemeyin veya boşaltmayın.

Asit veya alkali kimyasalların neden olduğu cilt tahrişi

- Substrat veya yıkama tamponu ile temas cilt tahrişine neden olabilir.
- Lütfen koruyucu cihazı taktığınızdan ve substratı veya yıkama tamponunu atarken reaktif talimatında belirtilen önlemleri uyguladığınızdan emin olun.

- Substrat veya yıkama tamponu cilde temas ederse, lütfen cildi hemen akan suyla yıkayın ve temas bölgesini dezenfekte edin. Gerekirse, lütfen tıbbi tavsiye isteyin.
- Reaktifi atarken lütfen koruyucu cihazı taktığınızdan ve reaktif talimatında belirtilen önlemleri uyguladığınızdan emin olun.

Yüksek voltajın neden olduğu elektrik çarpması

- Algılama ünitesinin bazı kısımları yüksek voltaj altında olduğundan elektrik çarpması riski vardır.
- Kapak plakasını algılama modülünden çıkarmayın.

Yangının neden olduğu yanık yaralanması

- Boyama reaktifi yanıcı bir maddedir, uygun şekilde kullanılmazsa yangına veya yanıklara neden olabilir.
- Hücreleri boya reaktifi ile boyarken ateşe yaklaşmayın.
- Boyama reaktifi hücre boyama için kullanılır ve inceleme ve imhadan kullanıcı sorumludur.

Bildirim Listesi

Sıvı atıkların uygun olmayan şekilde atılmasından kaynaklanan enfeksiyon

- Bulaşıcı patojenler (kan örnekleri) içeren sıvı atıklar, bulaşıcı tıbbi atıkların yönetiminden sorumlu yönetici tarafından ilgili yasa ve yönetmeliklere göre bertaraf edilmelidir.

- Reaktifte, kalibratörlerde ve kontrolde bulunan maddeler çevre koruma yasaları ile sınırlandırılmıştır ve bunların bertarafı, atık su ile ilgili yerel kalite standartlarına uygun olmalıdır.

Bulaşıcı atıkların uygunsuz şekilde imha edilmesi

- Atık maddeler bulaşıcı atıklara aittir ve bulaşıcı tıbbi atıkların yönetiminden sorumlu yönetici tarafından ilgili yasalara ve güvenlik kontrol yönetmeliklerine göre bertaraf edilmelidir.

Yetersiz numune tahliyesinden kaynaklanan hatalı ölçüm

- Numuneler lifli protein veya toz gibi çözünmeyen maddeler içeriyorsa, yetersiz numune absorpsiyonu nedeniyle test sonuçları hatalı olacaktır. Numuneleri yüklemeden önce numunelerde çözünmeyen maddeler olmadığından emin olunuz.

- Numune kabında hava kabarcıkları görünüyorsa, yetersiz numune absorpsiyonu nedeniyle test sonuçları hatalı olacaktır. Lütfen numuneleri yüklemeden önce numunelerde hava kabarcığı olmadığından emin olun.

Yanlış reaktif enjeksiyonundan kaynaklanan hatalı ölçüm

- Reaktif şişesinde hava kabarcıkları belirirse, yetersiz numune absorpsiyonu nedeniyle test sonuçları yanlış olacaktır.
- Lütfen reaktifi yüklemeden önce reaktifte kabarcık olmadığından emin olun.

Çalışma bölmesi kapağı ekstrüzyonundan kaynaklanan hasar

- Açma/kapama işlemi sırasında yaralanmayı önlemek için dikkatli çalışma yapılmalıdır.

Manuel kayıttan kaynaklanan yanlışlıkla reaktif absorpsiyonu

- Manuel kayıt sırasında reaktifin barkodu yanlış girilirse, yanlış reaktif kullanılması sonucunda test sonucu hatalı olacaktır.
- Manuel sistem ile reaktif kaydı sırasında, lütfen bu kullanım kılavuzunda belirtilen prosedüre göre reaktif barkod etiketi üzerindeki barkodu doğru bir şekilde girin.

Manuel kayıttan kaynaklanan kalibratörlerin veya kontrolün yanlış okunması

- Manuel kayıt sırasında kalibratörlerin veya kontrolün barkodu yanlış girilirse, yanlış kalibratörler veya kontrol kullanılması nedeniyle test sonuçları hatalı olacaktır.

- Lütfen manuel sistem ile reaktif kaydı sırasında bu kullanım kılavuzunda belirtilen prosedüre göre kalibratörün veya kontrolün barkod etiketi üzerindeki barkodu doğru bir şekilde girin.

Uzun süreli çalışmanın neden olduğu yorgunluk

- Uzun süre aynı hareketle LCD karşısında çalışıyorsanız vücudunuzda ve gözünüzde artan yorgunluk olabilir. Sağlığınız için her bir saat aralıksız çalışmadan sonra lütfen LCD karşısında 10-15 dakika ara veriniz. LCD'ye uzun süre bakmak günde 6 saati geçmez.

Uyarı işaretleri

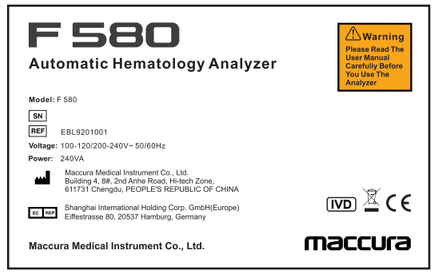
Aşağıdakiler Otomatik Hematoloji Analizörü üzerinde etiketlenmiş uyarı işaretleridir.
Lütfen her uyarı işaretini dikkatlice okuyun ve ilgili bileşenlerin içeriğini onaylayın.
Lütfen uyarı işaretlerini düzenli olarak kontrol edin ve güvenli mesafelerde net bir şekilde okunabildiklerinden emin olmak için temizlik ve bakım yapın. Uyarı levhaları eskime nedeniyle okunaksız ise değişim için lütfen firmanın servis departmanı ile iletişime geçiniz.

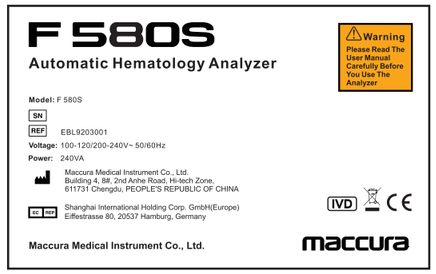
İşaretlerin açıklaması

Warning Uyarı Bu işaretin bitişiğindeki alanda ciddi yaralanma veya ölüme neden olacak bir tehlikeyi belirtir. Lütfen doğru kullanım için bu kullanım kılavuzunu dikkatlice okuduğunuzdan emin olun.	
Biohazard Warning Biyolojik Tehlike Uyarısı Bu işaretin bitişiğindeki alanda biyolojik tehlike olduğunu gösterir. Lütfen ilgili laboratuvar güvenlik prosedürlerine uyduğunuzdan emin olun.	
Waterproof Warning Su Geçirmez Uyarıso Sızmanın, bu işaretin bitişiğindeki alanda alete zarar verebileceğini gösterir. Bu alana sıvı koymayın.	
Mechanical parts Warning Mekanik parçalar Uyarısı Bu işaretin bitişiğindeki hareketli mekanik parçalara dokunulması durumunda olası bir tehlikeye işaret eder.	

İşaret

Bu alanın işlevini müşterilere anlatmak için işaretler kullanılır.
Alet tipi, kayıt bilgileri ve üretim numarası, alet arka panelinin isim plakasında etiketlenmiştir.





Operasyonda önleyici tedbirler

Otomatik Hematoloji Analizörünü doğru kullanabilmek için aşağıdaki hususlara dikkat ediniz:

Doğru test sonucunu sağlamak için notlar

- Cihaz çalışırken cihaz test modülü kapak plakasına dokunmayın, aksi takdirde test sonuçları yanlış olacaktır.
- Lütfen bakım parçalarını zamanında değiştirin; aksi halde test sonucu yanlış olabilir.

- Cihaz yüzeyini kirden uzak tutmak için numune alma iğnesini zamanında temizleyin, aksi takdirde alet arızası meydana gelir veya test sonucu yanlış olabilir.
- Süresi dolmuş reaktif, kalibratör ve kontrol kullanmadığınızdan emin olun. Süresi dolmuş ürünlerin kullanılması test hatasına neden olur ve test sonucu yanlış olur.
- Numuneleri, kalibratörleri veya kontrolü numune tüpüne uzun süre koymayın, aksi takdirde buharlaşma nedeniyle yoğuşur ve doğru bir şekilde analiz edilemez ve yanlış sonuçlara yol açabilir.
- Lütfen standart numune tüpü kullanın, aksi takdirde numunelerin yanlış absorpsiyon miktarı nedeniyle test sonucu yanlış olabilir.
- Reaktif eklemeye devam etmeyin, aksi takdirde çapraz kontaminasyona neden olarak yanlış sonuca neden olur.
- Test sırasında lütfen reaktif kabininin kapağını açmadığınızdan emin olun, aksi takdirde cihaz hatası olur veya test sonucu yanlış olur.
- Boru hattı dolumu her gün başlamadan önce yapılmalıdır, aksi takdirde hatalı sonuca neden olacaktır.

Cihaz hasarının önlenmesi için notlar

- Lütfen standart numune tüpünü kullanın; değilse, numune alma sistemi hasar görebilir.

- Numune iğnesi yıkama tankından sıvının taşması, devre kartının veya alt grubun hasar görmesi gibi cihaz arızalarına neden olabilir.
- Numuneyi veya reaktifi cihazın platformuna koymadığınızdan emin olun. Cihaz üzerine numune veya reaktif sıçraması, devre kartı veya alt montajın hasar görmesi gibi cihaz arızalarına neden olabilir.

Cihazın açılmasıyla ilgili notlar

- Kişisel yaralanmaya veya alet hasarına neden olabileceğinden, alet bakımı sırasında güç kaynağının değiştirilmesine izin verilmez.

Test başlangıcına ilişkin notlar

- Cihazın bakımının devam etmediğinden emin olun ve ardından yazılımın sağ penceresindeki başlat düğmesine tıklayın. Cihaz bakımı sırasında test başlarsa, bakım için kullanılan parçalar veya aletler, çalışan mekanizmaya dokunarak cihazda hasara neden olabilir.

Veri yedekleme

- Cihaz arızası veya hatalı çalışma durumunda test sonuçları kaybolacaktır. Güvenlik amacıyla, test sonucunun düzenli olarak yedeklenmesi önerilir.

Bilgisayar virüslerine karşı önlemler

- Ani bir program/veri bozulması olursa veya işlemde veya ekranda beklenmedik bir durum ortaya çıkarsa, bilgisayarınıza virüs bulaşmış olabilir.

- Bilgisayar virüsü, veri istisnasına veya bozulmasına neden olmak için bilgisayarınıza giren kötü amaçlı programları ifade eder.
- Bilgisayar virüslerine karşı koruma sağlamak için tasarlanmış programlara antivirüs programları denir.
- **Virüs enfeksiyonunun olası nedenleri:**
  Virüslü program iletişim sürecinde indirildi.
  Virüs bulaşmış USB sürücüsü veya diğer depolama ortamı yanlışlıkla kullanılıyor.

Not:

- Bir bilgisayara virüs bulaştığında, diğer bilgisayarlara iletişim veya depolama ortamı yoluyla bulaşma olasılığı yüksektir.
- Virüs şüphesi olan programları veya depolama ortamını kullanmadığınızdan emin olun.
- Mobil depolama ortamını kullanmadan önce lütfen antivirüs programı ile tarayın.

Güç kaynağının kesilmesi

- Güç kaynağının kesilmesi veya yıldırım düşmesi durumunda cihazın çalışma ünitesi bozulabilir ve yazılım sistemi, uygulama yazılımı ve veriler zarar görebilir.

Kontrol ünitesi

- Bir sabit diske veya başka bir depolama ortamına erişim sırasında, kontrol ünitesinde ani bir güç kaybı olursa, içinde saklanan veri/yazılımlar zarar görebilir. Kontrol ünitesini doğru kapatma yöntemi için lütfen kullanım kılavuzundaki ilgili bölümlere ve bölümlere bakın.

- Kontrol ünitesine başka programlar yüklemediğinizden veya ünite ayarlarını değiştirmediğinizden emin olun.
- Mobil ortamın göstergesi açıkken mobil ortamı çıkarmayın. Aksi takdirde cihaz veya mobil ortam zarar görecektir.
- Ekranın yanına manyetik testler koymadığınızdan emin olun. Aksi takdirde, bu testler hasar görecektir.

Elektromanyetik dalga girişiminin önlenmesi için notlar

- Cihazı elektromanyetik dalga girişimi kaynağının yakınına yerleştirmediğinizden emin olun, aksi takdirde girişim olabilir ve cihaz arızasına neden olacak şekilde test sonucu etkilenebilir.

Elektronik ürünlerin kirlilik kontrol işareti

Elektronik bilgi ürünlerinin kirliliğinin kontrolü ve yönetimine yönelik önlemlerin ilgili gerekliliklerine göre, ürünlere elektronik bilgi ürünlerinin kirlilik kontrol işareti bildirimi eklenmiştir.

Bu işaret, Çin Halk Cumhuriyeti'nde satılan tüm elektronik bilgi ürünleri için geçerli olan elektronik bilgi ürünleri için kirlilik kontrolü için kullanılır. Otomatik Hematoloji Analizörü aynı zamanda bir elektronik bilgi ürünüdür. Ortada işaretlenen sayı, ürünler için çevre koruma yılını temsil eder. Çevre korumanın ömrü, üründe bulunan toksik ve zararlı maddelerin veya elementlerin normal kullanım koşulları altında sızdırılmayacağı veya mutasyona uğratılmayacağı, kullanıcıların bu ürünü kullanmaları çevreye ciddi kirliliğe veya ciddi hasara neden olmayacağı zaman sınırıdır. kişi ve mal.

Toksik veya zararlı madde veya elementlerin adı ve içeriği

Bu üründeki toksik ve zararlı maddelerin veya elementlerin adı ve içeriği Tablo 1'de gösterilmektedir.

Tablo 1: Üründeki toksik ve zararlı maddelerin veya elementlerin adı ve içeriği

içerik		Toksik veya zararlı madde veya element					
		Plumbum（Pb）	Hidrargyrum（Hg）	Kadmiyum（Cd）	Altı değerli krom（Cr(VI)）	Polibromlu bifeniller（PBB）	Polibromlu difenil eterler（PBDE）
Otomatik Hematoloji Analizörür	Devre kartı	×	×	×	×	×	×
	Elektrik kablosu	×	×	×	×	×	×
	Mekanik parçalar	×	×	×	×	×	×
	Sıvı yolu sistemi	×	×	×	×	×	×
	Makine çerçevesi	×	×	×	×	×	×
	Dış kabuk	×	×	×	×	×	×
	PC（Kontrol bilgisayarı）	×	×	×	×	×	×
	Monitör	×	×	○	○	○	○
	Yazıcı	×	○	○	○	○	○
	ID ünitesi (barkod okuyucu ünite)	×	×	×	×	×	×

○：Bileşenin tüm homojen malzemelerindeki toksik ve zararlı madde içeriğinin SJ/T 11363-2006 işaretinde belirtilen limitin altında olduğu belirtilmektedir.

×：Bileşenin en azından belirli bir homojen malzemesindeki toksik ve zararlı madde içeriğinin SJ/T 11363-2006 işaretinde belirtilen sınır gerekliliklerinin ötesinde olduğu belirtilmektedir.

Bölüm 1
Kılavuza Genel Bakış

1.1 Genel Bakış

Bu bölüm Otomatik Hematoloji Analizörü kılavuzunun nasıl kullanılacağını açıklar. Bu kılavuz cihazla birlikte gelir ve analizörün kullanımı, işlevi ve kullanım yönteminin ayrıntılı bir açıklamasıyla birlikte sağlanır. Analizörü kullanmadan önce, analizörün doğru kullanımını sağlamak, en iyi performansını gerçekleştirmek ve operatör güvenliğini sağlamak için lütfen bu kılavuzu dikkatlice okuyun ve anlayın.

Önemli:

- Lütfen cihazı kesinlikle kılavuza göre kullanın.

1.2 Uygulama Aralığı

Bu kılavuz, tıbbi muayene uzmanları veya eğitimli doktorlar, hemşireler ve laboratuvar teknisyenleri için geçerlidir. İçin kullanılır:

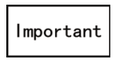
- Cihaz donanımını ve yazılımını anlama
- Sistem parametrelerinin ayarlanması
- Numunenin rutin analizi
- Sistem bakımı ve sorun giderme gerçekleştirme

1.3 Ortak çalıştırma

İsim	İşletme
tıklama	İlgili konuma veya düğmeye sol tıklayın, bazen düğmeyi çift tıklamanız gerekir.
giriş	Giriş veya düzenleme kutusuna tıklayın, giriş kutusunda imleç belirir, gerekli bilgileri (harfler, karakterler, sayılar, semboller, vb.) girmek için klavyeyi kullanın.
silme	Farenin sol düğmesini tıklayın (veya ↑ ↓ ← →) imleci silme yerine yerleştirmek için, geri al tuşu bilgiden önceki imleci silmek için, sil tuşu imleç bilgisini silmek için, sil tuşu imleç bilgisini silmek için.
kaydırma çubuğu sürükleme	Sayfa çevirme işlemini gerçekleştirmek için farenin sol düğmesi kaydırma çubuğunun her iki yanındaki oka tıklayın; Veya kaydırma çubuğunu seçmek için fareyi, sayfayı çevirmek için fareyi hareket ettirin.
açılır liste seçimi	Fare tıklaması açılır kutusu aşağı oku, açılır açılır liste listesi, hareketten sonra fare tıklaması veya klavye ↑ ↓ tuşuna basarak onaylamak için Enter tuşunu seçin.

1.4 Sembol açıklaması

Kılavuzda aşağıdaki semboller kullanılmıştır, sembolik anlamları aşağıdaki gibidir:

semboller	anlam
	Operatörden semboldeki talimatlara göre çalıştırması istenir, aksi takdirde kişisel yaralanmaya neden olabilir.
	Operatörden semboldeki talimatlara göre çalışması istenir, aksi takdirde analizör arızası, hasar veya test sonuçlarını etkileyebilir.
	Operatörden, semboldeki talimatlara göre çalıştırması istenir, çalıştırma adımındaki önemli bilgileri veya operatörün özel dikkat göstermesini gerektiren içeriği vurgulayın.
	Operatörden semboldeki talimatlara göre çalışması istenir, aksi takdirde potansiyel biyolojik bulaşıcılık tehlikesi vardır.
	Normal çalışmada kapıları veya kapakları açmayın, kapıyı veya kapağı açmanız gerekiyorsa ilgili eğitimi almış kişi tarafından yapılmalıdır.
	Operatörden semboldeki talimatlara göre çalıştırması istenir, aksi takdirde ürün bileşenlerinde hasara neden olabilir, bu da test sonucunu etkileyebilir veya kişisel yaralanmaya neden olabilir.

Analizörde, reaktif ambalajı, kalite kontrol ürünleri veya kalibrasyon ürünleri aşağıdaki işaretleri gösterebilir:

semboller	anlam
	**Uyarı işaretleri**
	**Yüksek basınç uyarısı**
	**Işık uyarısından kaçının**
	**Biyolojik kirlilik**

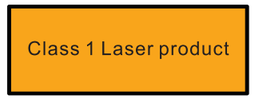
	**Yüksek sıcaklık uyarısı**
	**Koruyucu Topraklama**
	**Alternatif akım**
	**Üretici**
	**Üretim tarihi**
	**Talimatlara bakın**
	**Seri Numarası**
	**Sadece in vitro tanı için kullanılır.**
	**Son kullanım tarihi**
	**Ölçüm lisansı**
	**Depolama sıcaklığı**
	**Parti numarası**
	**Antistatik etiketleme**
	**Elektronik bilgi ürünü kirlilik kontrol işareti**

1.5 Lazer Girişi

Lazer tipi	Dalgaboyu	Güç	Maksimum çıkış	Yatay İletim Açısı	Dikey İletim Açısı
Liste 3B	635nm	3.5mW	5mW	8°	31°

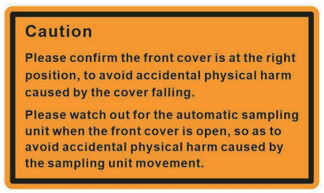
Cihazın dışında veya içinde aşağıdaki lazer uyarı etiketlerini görebilirsiniz, lazer hasarını önlemek için lütfen talimatları izleyin!

Bu etiket, optik bileşen lazer koruma kutusuna yapıştırılmalıdır.



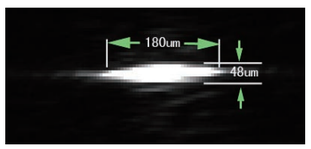
Bu etiket gövde kabuğuna yapıştırılmalıdır.

Bu etiket, makinenin içindeki optik bileşen lazer koruma kutusuna yapıştırılmalıdır.



Bu etiket cihaz kapağına yapıştırılmalıdır.

Lazer odak noktası boyutu:



1.6 Uyarı

Warning Uyarı

- Bu sistem sadece şirketimiz veya şirketimizin distribütörleri tarafından eğitilmiş profesyonel tıp doktorları, doktorlar veya laboratuvar operatörleri tarafından kullanılabilir.
- Analizörden sorumlu hastane veya kurum iyi bir bakım planı sağlayamazsa normal analizörün arızalanmasına ve insan sağlığının tehlikeye girmesine neden olabilir.

- Lütfen analizörü çalıştırma talimatlarına göre kullandığınızdan emin olun. Çalışma koşulu, kullanım kılavuzunda belirtilenleri aşarsa, analizör normal şekilde çalışmayabilir ve test sonuçları güvenilir olmayabilir ve analizör bileşenlerine ve insan güvenliğine zarar verebilir.
- Analizör iyi topraklama koşullarında kullanılmalıdır.
- Analiz cihazı belirtilen sigortayı kullanmalıdır.
- Lütfen voltajın gereksinimleri karşıladığını onaylayın.
- Cihazı elektromanyetik parazit kaynağının yakınına koymayın, aksi takdirde müdahale edilecek ve test sonucunu etkileyecek ve hatta cihazın arızalanmasına neden olacaktır.

- Tehlikeyi önlemek için analizör yanıcı ve patlayıcı ortamlarda kullanılmamalıdır.

- Analizörü yetkiniz olmadan hareket ettirmeyin. Taşınmanız gerekiyorsa, lütfen şirketin servis departmanıyla iletişime geçin.
- Reaktifler gözleri, cildi ve mukoza zarlarını tahriş edebilir. Operatörler, laboratuvar güvenlik yönetmeliklerine uymalı ve temas reaktifleri ile ilgili öğeleri (Laboratuvar koruyucu önlükleri, eldivenler vb.) kullanırken kişisel koruyucu ekipman giymelidir.

- Reaktif cilt ile temas ederse, hemen temizlemek için su kullanın veya gerekirse doktorlara danışın.
- Reaktiflerin, atık sıvının ve atık numunenin boşaltılması, ilgili ülkedeki, reaktif ve atık sıvı için olası muayene malzemelerinin boşaltılması ve bertarafı ile ilgili yönetmeliklere uygun olmalıdır.

- Numune iğnesi çok ince olduğundan ve olası incelemelere kalibratörler, kalite kontroller ve numuneler neden olacaktır. Lütfen işlem sırasında dikkat edin.

- Atık kalibratörlerinin imhası ve kalite kontrol paketi, reaktif ve atık sıvı için olası muayene malzemelerinin boşaltılması ve bertarafı ile ilgili olarak ilgili ülkedeki yönetmeliklere uygun olmalıdır.

- Analizörü yalnızca şirketimiz tarafından onaylanan mühendisler ve operatörler çalıştırabilir ve bakımını yapabilir, aksi takdirde zararlı radyasyon hasarına neden olabilir.

- Normal çalışma sırasında lazer kalkanını açmak yasaktır. Koruyucu kapakta gevşek veya büyük boşluk varsa lütfen en kısa sürede şirketimizle iletişime geçin.

1.7 Bildirim

Important **Önemli**

- Bu talimatın okuyucusu, aşağıdaki klinik departmanda bulunan aşağıdaki profesyonel personeldir:
  1. Günlük sistem işleyişini gerçekleştiren personel;
  2. Sistem bakım ve sorun giderme işlemlerini gerçekleştiren personel;
  3. Sistem bakımlı ve canli canli personel;
- Lütfen aşağıdaki talimatları kesinlikle takip edin.
- Analizör klinik tarama için kullanılır. Doktor analitik sonuçlara göre karar verirken, klinik test sonuçları veya diğer test sonuçları aynı anda dikkate alınmalıdır.
- Reaktiflerin saklanması ve kullanımı için lütfen reaktif talimatlarına bakın.
- Analiz cihazını kullanmadan önce reaktifin kalan miktarını günlük olarak kontrol edin ve günün numunesi için yeterli olup olmadığını tahmin edin. Reaktif için herhangi bir eksiklik varsa, zamanında hazırlanmalıdır.
- Herhangi bir reaktifin değiştirilmesinden sonra, ölçülen değerlerin izin verilen arka plan aralığında olduğundan emin olmak için bir arka plan kontrolü yapılmalıdır ve numune testi ancak kalifiye olduktan sonra yapılabilir.

- Reaktif, saklama sıcaklığından oda sıcaklığına geri getirilmelidir.

- Açık kutu veya kurulum işlemi sırasında firmamız tarafından yetkilendirilmemiş veya eğitilmemiş personel cihaza zarar verebilir, lütfen şirketimiz tarafından yetkilendirilmiş personel burada değilken kutu veya tesisat analizörünü açmayınız.

- Lütfen analizörün üstüne reaktifler veya başka sıvılar koymayın.
- F 580 yazılımının gücü ile analizörün gücü arasında bir sıralama yoktur ve bunlardan biri rastgele seçilebilir.
- Operatör temiz bir EDTA-K2 antikoagülasyon vakumlu kan alma tüpü, silisli cam tüpler, plastik test tüpleri, santrifüj tüpleri ve silikon boratlı cam kapiler kullanmalıdır.

- Manuel tam kan modunda numune miktarı 1 mL'den az değildir.
- Beyaz kan hücresi sınıflandırması veya trombosit sayımı için kullanılan numuneler ortam sıcaklığında saklanmalı ve alındıktan sonra 4 saat içinde analiz edilmelidir.

- Trombosit sınıflandırmasının sonuçları, ortalama kırmızı kan hücresi hacmi veya lökosit sınıflandırması gerekli değilse, 2℃～ 8℃'de 24 saat saklanabilir.
  Soğutulduktan sonra, numuneler analizden önce en az 30 dakika ortam sıcaklığında tutulmalıdır.
- Bir süre haşlandıktan sonra numune yeniden karıştırılmalıdır.
- Periferik kan ve seyreltici, test edilmeden önce 3 dakika süreyle yerleştirilmelidir.

- Lütfen kapiler kan örneğinin seyreltmeden sonra 30 dakika içinde test edildiğinden emin olun.

- Laboratuvar, numune sayısına, numune toplama yöntemine ve teknik seviyeye bağlı olarak ön seyreltme modunda test sonuçlarının stabilitesini değerlendirmelidir.

- “***”, depoya girilen numune numarasını temsil eder.
- Lütfen örnek tüpünü çıkarırken örnekleme iğnesine dokunmayın ve örnekleme iğnesinin çarpışmasını veya tüpe kan girmesini önleyin.

- Bir numunenin analizini bitirdikten sonra, durum çubuğu ekran numune numarası otomatik olarak +1 artacaktır, bu nedenle iş listesi kayıt sırasına göre kaydedildiği sürece, test işlenirken müdahale etmek için manuel numune numarasına gerek olmayacaktır.
- Analizörün güvenilirliğini ve kararlılığını garanti etmek için, kapatma prosedürünü uyguladığınızdan emin olun.
- Kullanıcılar kapatma programını iptal etmek isterse, lütfen kapatma iletişim kutusundaki “iptal” -"cancel"- düğmesine tıklayın ve ardından ölçüm hazır durumuna geri dönün.
- Gücü kapattıktan sonra, ana bilgisayarla etkileşimi olmayan F 580 yazılım çalışma sayfasını, sonuç görünümünü, sonuç yazdırmayı ve diğer işlevleri kullanmaya devam edebiliriz.

- Parti seçiminin sonuçları yüksek parlaklıkta görüntülenir, Sonuç görüntüleme sütunu yalnızca sol listede belirtilen numune okunu görüntüler.
- "QC-" ile başlayan numune numarası kalite kontrol verileridir ve değiştirilmesine izin verilmez.
- Denetim durumu, denetim sütununda “S” etiketi ile gösterilir.
- Kalite kontrol verileriyle karıştırılmaması için numune numarasının "QC-" veya "qc-" ile başlayacak şekilde değiştirilmesine izin verilmez.
- İletişim kutusundaki sayı, kullanıcı toplu seçimi tarafından seçilen sonuçların sayısıdır.
- Raporu yazdırmadan önce, lütfen yazıcı kurulumunun bağlantılarının iyi durumda olduğunu ve kağıtların yeterli olduğunu onaylayın.
- Dosyalar sistem tarafından otomatik olarak üretilir ve kullanıcılar gerektiğinde onları yeniden adlandırabilir.
- Türü tek biçim CSV olarak kaydedin.
- Numune CBC+DIFF test modunu gerçekleştirdiğinde, WBC histogramının gerçek görüntüsü BASO sınıflandırma rakamıdır.
- Ekranı büyütmek için grafiğe çift tıklayın.
- İncelenen sonuçlar, inceleme durum çubuğunda mavi arka planda gösterilir ve incelenmeyen sonuçlar beyaz arka planda gösterilir.
- "QC-" ile başlayan numune numarası, tarayıcı veya yöneticide yazdırılamayan kalite kontrol verileridir. QC çizelgesi arayüzünde kalite kontrol baskı formatında çıktısı alınmalıdır.
- Yalnızca yönetici ayrıcalıklarına sahip oturum açan kullanıcılar kalibrasyonu gerçekleştirebilir.
- Kullanıcı, şirket tarafından belirlenen kalite kontrol ürünlerini ve kalibrasyonlarını ve kesinlikle saklama için kalibrasyon, kalite kontrol ve reaktiflerin belirtilen saklama ortamına uygun olarak kullanacaktır.
- **Hassas test yöntemi:** Tam kan testi modunda, orta seviye kalite kontrolünü sürekli olarak 10 kez test edin, sonuçları CSV formatına aktarın ve CV değerlerini saymak için Excel'i kullanın.
- Yalnızca öngörülen kalite kontrol ürünleri kullanılabilir. Ve kalite kontrol ürünlerine uygun olarak depolama ortamını belirtecektir.

- Yalnızca öngörülen kalite kontrol ürünleri kullanılabilir. Kalite kontrol ürünleri, analizörün analiz durumunu değerlendirmek için kullanılır.
- Parti numarası girilmediğinde onay düğmesi etkinleştirilmez.
- Kayıtlı belge numarasını değiştirmek için Enter'a tıklayın, kalite kontrol materyalleri değiştirilemez.
- Seçilen belge boş olduğunda ve parti numarası bilgisi girilmediğinde sil düğmesi etkinleştirilmez.
- Onay iletişim kutusu “Tamamen [1] ” -“Totally [1] ”-, sayı, silinecek mevcut seçili belge sayısını temsil eder.
- Yanlış bakım analizöre zarar verebilir. Operatör, teknik özelliklere göre bakım yapmalıdır.
- Kullanım kılavuzunda net bir sorun yoksa, profesyonel personel tarafından bakım tavsiyesi vermek için lütfen şirketimizin servis departmanı ile iletişime geçin.

- Analiz cihazının bakımı firmamız tarafından sağlanan parçalar kullanılarak yapılmalıdır. Herhangi bir sorunuz varsa, lütfen servis departmanımızla iletişime geçin.
- Bu kılavuz bir bakım kılavuzu değildir. Yalnızca, analizör arızalandığında veya alarm verdiğinde operatörün alması gereken önlemleri sağlar.

1.8 Biyolojik risk

- Numuneler, kalibratör, kalite kontrol materyali ve atık sıvı potansiyel biyoenfeksiyon riski taşır Lütfen laboratuvar güvenlik çalışma kurallarına uyun ve kişisel koruyucu ekipman (laboratuvar koruyucu giysisi, eldiven vb.) giyin.

- Hastanın kan örnekleriyle doğrudan temas kurmayın.
- Analizörün tüm parçaları potansiyel olarak biyoenfeksiyözdür ve çalıştırma ve bakım sırasında güvenlik önlemleri alınmalıdır.

Bölüm 2
Sistem Girişi

2.1 Genel Bakış

Otomatik Hematoloji Analizörü bir in vitro teşhis ekipmanıdır ve destekleyici reaktifler, kalibratörler ve kalite kontrol materyali ile birlikte kullanılır. Tıbbi laboratuvarda kan hücrelerini kantitatif olarak analiz etmek ve WBC üzerinde 5 parçalı farklılaşma yapmak için kullanılır.

2.2 Kapsam ve Kontrendikasyonlar

Analizör, insan kan örneklerini test etmek, kanın görünür bileşenlerinin kalitatif ve kantitatif analizini yapmak ve ilgili bilgileri sağlamak için geçerlidir.

Important	■ Analizör, klinik tarama için bir araçtır. Doktorlar, analiz sonuçlarına dayanarak karar verirken klinik muayene sonuçlarını veya diğer test sonuçlarını dikkate almalıdır. ■ Kontrendikasyonlar: Bu analizör klinik antikoagülan testlerinde kullanılır ve numunelerde pıhtılaşma ve hemoliz olmaması gerekir.

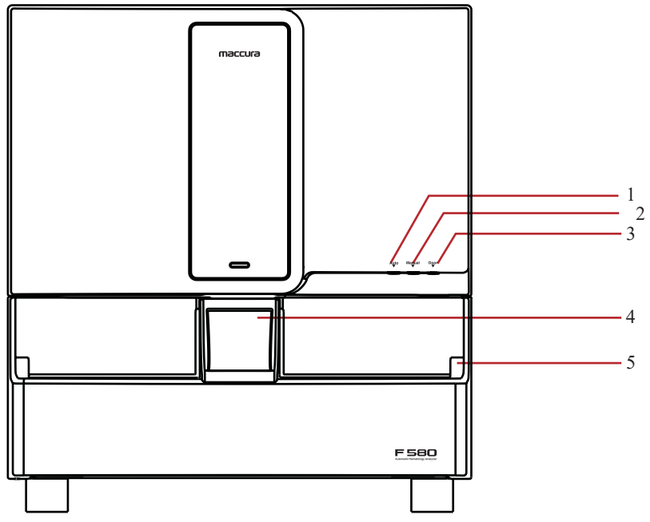
Aşağıdaki 24 rapor parametresinin ve 4 araştırma parametresinin, 3 histogramın ve 1 dağılım grafiğinin nicel analizi sağlanır.

	İsim	Kısaltma	CBC	CBC + DIFF
CBC Parameters	White Blood Cell Count	WBC	※	※
	Red Blood Cell Count	RBC	※	※
	Hemoglobin	HGB	※	※
	Mean Corpuscular Volume	MCV	※	※
	Mean Corpuscular Hemoglobin	MCH	※	※
	Mean Corpuscular Hemoglobin Concentration	MCHC	※	※
	RBC Distribution Width-Coefficient of Variation	RDW-CV	※	※
	RBC Distribution Width-Standard Deviation	RDW-SD	※	※
	Hematocrit	HCT	※	※
	Platelet Count	PLT	※	※
	Mean Platelet Volume	MPV	※	※
	Platelet Distribution Width	PDW	※	※
	Platelet Hematocrit	PCT	※	※
DIFF Parameters	Basophilic Granulocyte Count	BASO#	/	※
	Basophils Percentage	BASO%	/	※
	Neutrophile Granulocyte Count	NEUT#	/	※
	Neutrophile Granulocyte Percentage	NEUT%	/	※
	Eosinophilic Granulocyte Count	EO#	/	※
	Eosinophilic Granulocyte Percentage	EO%	/	※
	Lymphocyte Count	LYMPH#	/	※
	Lymphocyte Percentage	LYMPH%	/	※
	Monocyte Count	MONO#	/	※
	Monocyte Percentage	MONO%	/	※
	Other Cells Count (research)	OTHER#	/	/
	Other Cells Percentage (research)	OTHER%	/	/
	Immature Granulocyte Count (Research)	IG#	/	/
	Immature Granulocyte Percentage (Research)	IG%	/	/
Histograms	White Blood Cell Histogram	WBC Histogram	※	※
	Red Blood Cell Histogram	RBC Histogram	※	※
	Platelet Histogram	PLT Histogram	※	※
Scattergram	Differentiation Scattergram	4 DIFF scattergram	/	※

“※” bu parametrenin bu mod altında test edildiğini;
“/”, bu parametrenin bu modda sağlanmadığını gösterir.

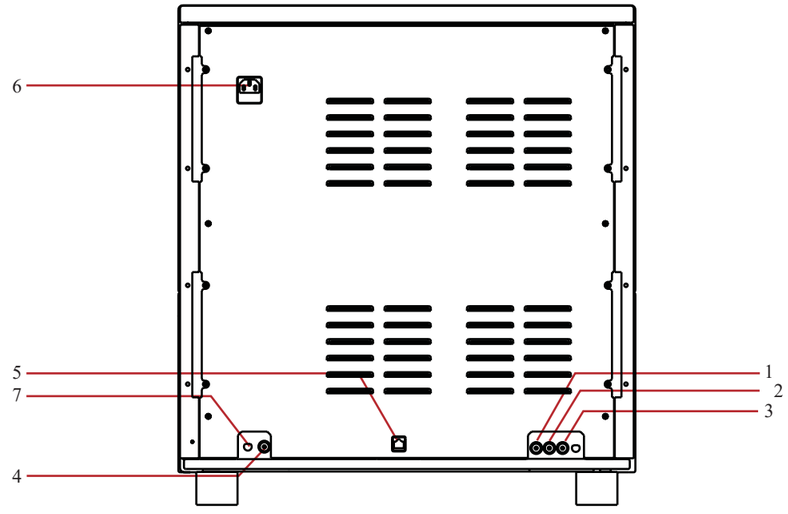
2.3 Ürünün Yapısı ve Bileşenleri

Analizör esas olarak ana bilgisayar ve aksesuarlardan oluşur.



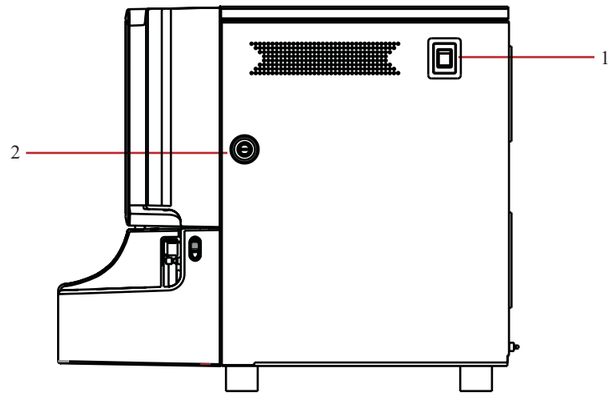
Şekil 2.3-1

1	Otomatik Numune Alma Butonu
2	Manuel Numune Alma Butonu
3	Acil Kapı Açma Butonu
4	Kapalı Numune Alma Konumu
5	Ön Panel Açma Butonu



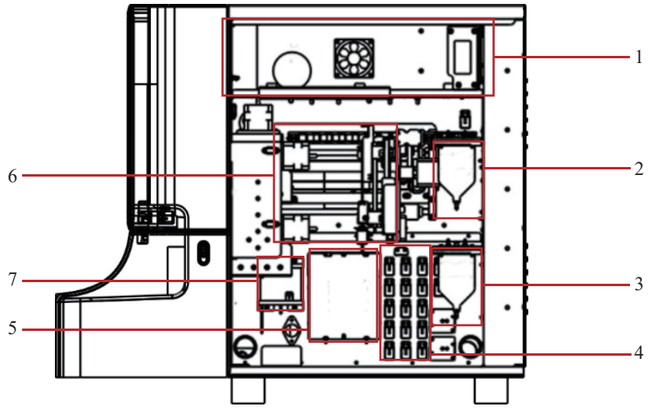
Şekil 2.3-2

1	LH-5 Lysing Reaktif Arayüzü	5	Ağ Hattı Arayüzü
2	LD-5 Lysing Reaktif Arayüzü	6	Güç Kablosu Konektörü
3	GD-5 Diluent Arayüzü	7	Sensör Arayüzü
4	Sıvı Atık Arayüzü		



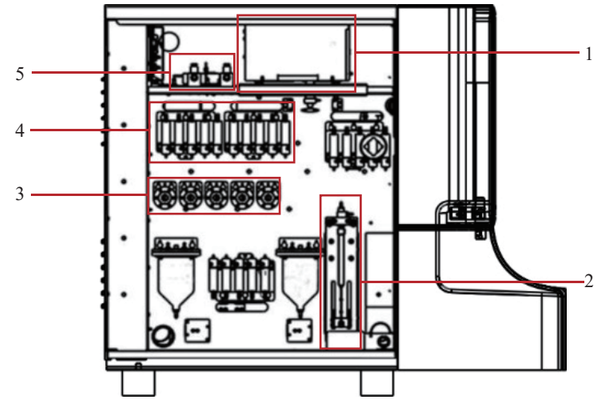
Şekil 2.3-3

1	Güç Butonu
2	Kapı Kilidi



Şekil 2.3-4

1	Güç	5	WBC, RBC Dedektör Bloğu
2	Negatif Basınç Odası	6	Numune Toplama Ünitesi
3	Atık Sıvı Odası	7	DIFF Odası
4	Sıvı Valfi		



Şekil 2.3-5

1	Optik Sistem
2	Şırınga
3	Dozaj Pompası Cihazı
4	Sıvı Valfi
5	Kontrol Vanası

2.3.1 Durum Gösterge Işığı

Durum gösterge ışığı, analizörün ön tarafında bulunur. Analizörün şu anda Hazır veya Hazır Değil durumunda olup olmadığını görüntüler.

2.3.2 Aspirasyon Pipeti

Aspirasyon pipeti, analiz cihazının önünde bulunur. Kantitatif kan örneklerini doğru bir şekilde çizer.

2.3.3 Örnekleme başlatma düğmesi

Analizörün ön tarafında bulunan örnekleme başlatma düğmesi, ilgili zamanlama analizörünün uygulanmasını tetikler.

2.3.4 Cihaz Arayüzü

- **Güç Arayüzü**
  Ağa bağlanacak güç kablosunun takılması içindir.

- **Reaktif Atık Arayüzü**
  Analiz cihazını çeşitli destekleyici reaktiflere ve tüplerle atık kovasına bağlamak içindir
- **Ağ Hattı Arayüzü**
  TCP / IP protokolü ile uyumlu dahili 100M ağ kartı. Analizörün destekleyici yazılımıyla iletişim kurmak için kabloyu takın, uygun komutu verin ve analiz verilerini yükleyin.
- **Sensör arayüzü**
  Atık şişesinin dolu olup olmadığına karar vermek içindir.

Important	■ Cihaza bağlanan bilgisayar GB 4943.1'in ilgili standartlarını karşılamalıdır.

2.3.5 Güç anahtarı

Güç anahtarı, analizörün sağ tarafında bulunur. Gücü bağlamak ve kesmek için kullanılır.

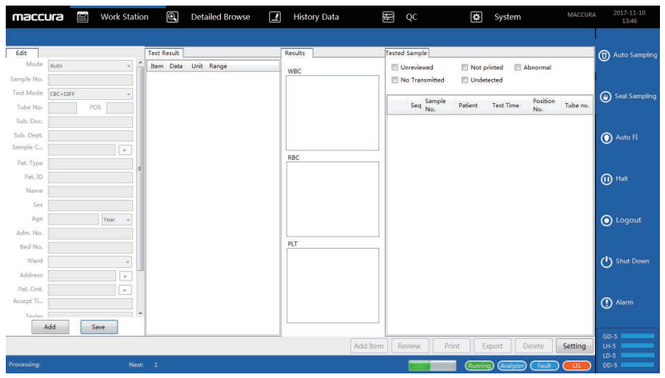
2.3.6 Yan kapı kilidi

Yan kapı kilitleri, analizörün kolay bakım veya onarımında yan kapıyı açmak için analizörün sol ve sağ taraflarında bulunur.

2.4 Arayüz

2.4.1 Ana arayüz

Masaüstündeki ikona çift tıklayın, açılıştan sonra Şekil 2.4.1-1'deki ana arayüz ekrana gelecektir. İlgili fonksiyon arayüzüne girmek için simgeye çift tıklayın.



Şekil 2.4.1-1

2.4.2 Ana İşlev

İlgili düğmeye tıklayarak, farklı işlevleri gerçekleştirmek için ilgili işlev arayüzüne girebilirsiniz.

Tuş	**Fonksiyon**
Work station	Register work list sample View the sample analysis results Review, check, print sample result
History data	Different ways to review the analyzed sample results Query the analyzed sample results
Detailed browser	Check the results of an analyzed sample in detail
QC	Register or view quality control documents View quality control history with quality control chart Perform quality control analysis
Basic data	Register, modify, check the information of the patient, doctor, department and ward building
Maintenance	Perform maintenance operations
Setting	Set the related functions
System	Perform the operation of calibration, dormancy, switch user, logon audit, shutdown, view instrumentation information.

2.4.3 Fonksiyonel arayüz

- **Menü arayüzü**
  Tıklamak ve açmak için 5 menü düğmesi sağlar.
- **Kısayollar Alanı**
  İlgili işlevleri gerçekleştirmek için tıklayın

Şekil 2.4.3-1

- **Cihaz Durum Arayüzü**
  Cihazın mevcut durumunu görüntüler

→ Status-Analyzer
Meaning: network status of software and instrument, divided into unconnected (red) and connected (blue). →
Status-LIS
Meaning: The connection state between the program and LIS, divided into unconnected (red) and connected (blue).
→ Status-fault
Meaning: The current fault status of the analyzer, divided into failure (red), normal (blue).
→ State-runing
Meaning: The running status of the analyzer, divided into unready (red), ready（ blue ） and running (green).

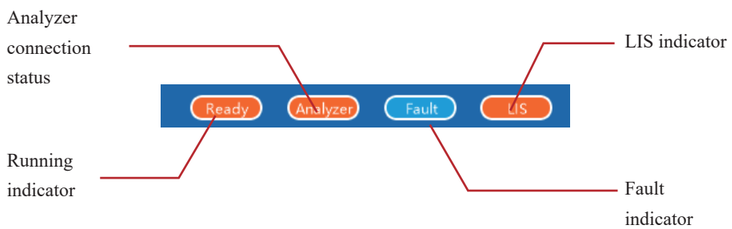


Figure 2.4.3-2

- Analyzer operation
  4 buttons including autosampling, closed sampling, automatic fluid injection, and pause can perform related operations.

→ Autosampling
When the instrument is ready without mulfunction, click the autosampling button, and the instrument performs autosampling, which corresponds to the autosampling measurement button on the instrument .

→ Closed sampling

When the instrument is ready or autosampling is paused without mulfunction, click the closed sampling button to perform closed sampling operation, which corresponds to the manual sampling button on the instrument.

→ Automatic liquild injection

When the analyzer is ready and without alarm, click the automatic liquild injection button and the instrument can be operated automatically. → Pause

In the process of autosampling, click pause button, the instrument will pause after the test of current sample, the user can perform closed sampling or maintenance operations when the instrument is paused.

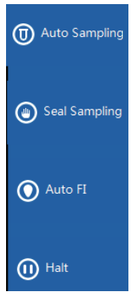


Figure 2.4.3-3

The following areas are used for related sample information, including: → Test information area

- Show the current sample and the next sample number to be tested.

→ Analysis setting area

- Click different mode, the dialog box below will show up.
- Closed sampling:

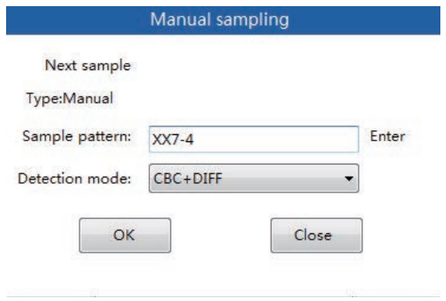


Figure 2.4.3-4

- AutoSampling

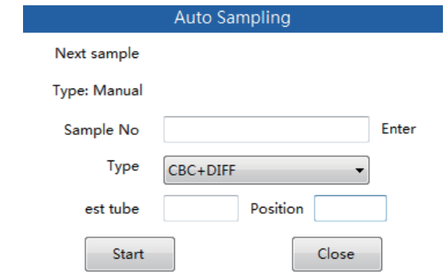


Figure 2.4.3-5

→ Fault information area

Display fault information, if the number of faults is too large, it can be displayed by rolling. Click the button“Clear Alarm”to eliminate the fault, click the button “Stop Beep”to eliminate the alarm sound when the current fault occurs.

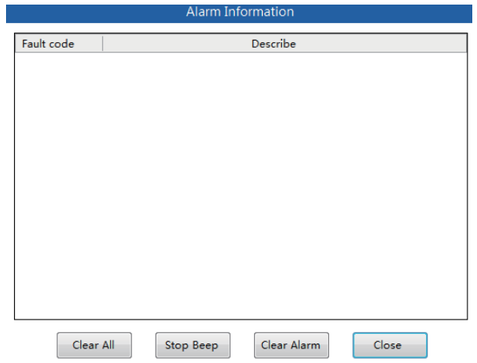


Figure 2.4.3-6

2.5 Samples and sample rack description

2.5.1 Sample classification description

The sampling methods are automatic sampling amd closed sampling, the quality control sample, calibration sample, and background checking sample are all classified as closed sampling.
According to the way of sample generation (or matching), it is divided into non scanning generation and scanning production samples. Non scanning generation is also divided into work sheet samples, automatically generated samples
(automatic increments). The scanning mode requires the apparatus to configure the bar code scanning module.
The worksheet sample can be registered before the test, and the untested worksheet sample number is not allowed to repeat.
Every day the sample number starts from "1", and if the work sheet has
already registered the sample "1", it begins to measure from the work sheet. Automatically generated samples are generated automatically during the measurement process (Before the measurement, the user can set the number from which to start). The last sample is +1 based on the previous one, for example, the former one is "S1", and the latter one is "S2".
The sample number generated by the scan is the barcode number, and the barcode is scanned by the analyzer during the measurement. Scanning match mode requires the support of analyzer's scan module.

2.5.2 Sample rack description

1. The sample rack number is represented by a positive integer and the interval is [1-999].

2. The sample rack generation method is divided into 2 categories, generated through editing when user registers work sheet sample and automatically generated during measurement, the sample rack number of unfinished measurements samples are not allowed to repeat.
3. The automatic generation of sample rack number is the previous one +1, starting from 1 everyday.

2.6 Reagents, Calibrators and Quality Control Materials

Analyzer, reagents, calibrator and control material constitute a system together, and must be used as a whole to ensure overall performance.
Reagents must be designated by maccura, otherwise the reliability and accuracy of analytical results cannot be ensured, and may cause damage to the analyzer. "Reagent" in this manual all refer to supporting reagents of the analyzer. Each reagent's package integrity and validity must be checked before usage. Make sure that no package is damp or leaking, and the reagent must be used within the period of validity.

Important	Note: ■ Please refer to instructions for reagent storage and usage. ■ Check reagent remaining before using analyzer, and estimate whether reagent remaining is enough for the day, if not please prepare in advance timely. ■ Background should be checked after changing any reagent to ensure that the measured value is within the allowable range. The samples only can be tested after passing background test. ■ Reagents should recover from storage temperature to room temperature when being used.

2.6.1 Reagent

- Automatic Hematology Analyzer GD-5 Diluent A
- Diluent is an isotonic solution that has a specific conductivity, provides a stable environment for the blood count and conducts pipe cleaning after completion of the test.
- Automatic Hematology Analyzer LH-5 Lysing Reagent A Dissolve erythrocytes to conduct HGB measurement.
- Automatic Hematology Analyzer LD-5 Lysing Reagent A Dissolve erythrocytes and divides leukocytes into 4 categories.
- Automatic Hematology Analyzer DD-5 Fluorescent Dye A Stains nucleic acid of leukocytes and differentiates leukocytes.
- Automatic Hematology Analyzer CC-5 Cell Clean A
  It contains detergent which can remove stains in the tubes. It is used for routine instrument cleaning and maintenance.

2.6.2 Quality Control Material and Calibrator

Quality control materials and calibrator are used for quality control and analyzer calibration.

"Quality control material" and "Calibrator" mentioned in this manual refer to maccura designated quality control material and calibrator, which must be purchased from maccura or maccura agents.

Chapter 3 Design Principles

3.1 Overview

The analyzer uses electrical impedance method to measure the number of red blood cells and platelets; uses colorimetric method to measure the concentration of hemoglobin; and uses semiconductor laser flow cytometry technique to count WBC and classify five-diff WBC.
And calculate the remaining parameters according to the corresponding equations.

3.2 Samples Extraction

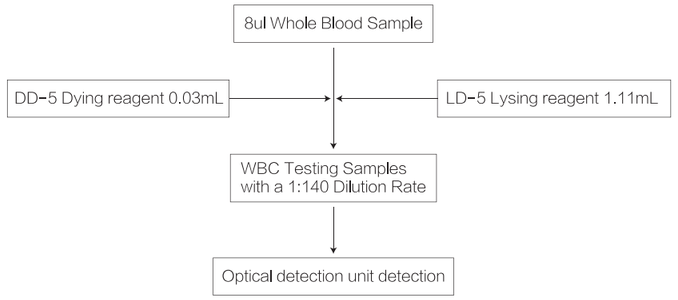
The analyzer provides an open sampling method.
Open sampling supports whole blood and pre-dilution mode.
Under open whole blood mode, the analyzer will draw 20μl of whole blood samples.
Under open pre-dilution mode, the operator will first mix 20μl peripheral blood sample with 200μl dilution to form a sample of 1:11 dilution outside the analyzer. Then the analyzer will draw 91.5μl diluted sample.

3.3 Sample Dilution

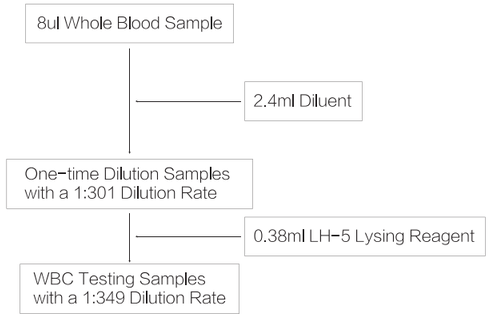
After blood samples are collected, blood will be distributed and diluted according to different measurement parameters, and then be used for leukocyte differentiation and counting, hemoglobin measurement, and erythrocyte counting and measurement.
Based on the different options of the user, the analyzer provides two operation modes: whole blood mode and pre-dilution mode.

3.3.1 Whole Blood Mode

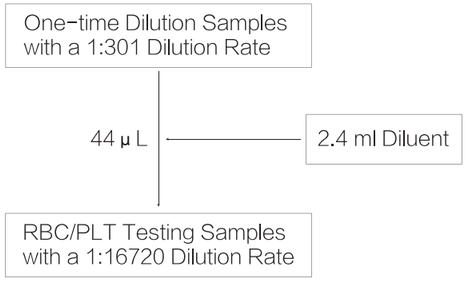
- WBC Differentiation Dilution Process



■ WBC Counting / HGB Dilution Process



■ RBC/PLT Dilution Process



3.4 WBC Measurements

3.4.1 WBC Differentiation (Semiconductor Laser Flow Cytometry)

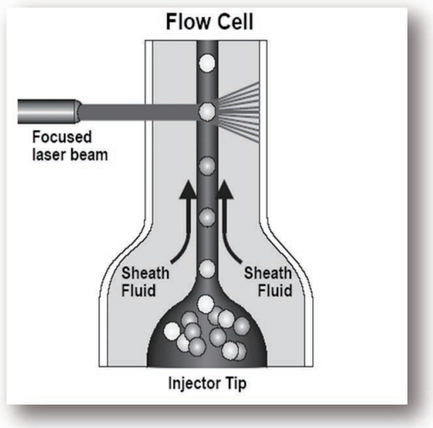


Figure 3.4.1-1

When certain amount of blood cells are drawn and reacted with specific reagent, certain amount of blood samples will be injected through the nozzle into the conical flow chamber which is filled with diluent. With the surrounding of sheath fluid formed by diluent, the cells will cross the central flow chamber in a single row. When the blood cells which are floated in the sheath fluid pass through the laser detection region, they will be exposed to a laser beam and produce scattered lights, whose property is associated with the cell size, cell membrane and refractive index of the internal cell structure.

The forward scattered light reflects the size of the cells, the side scattered light reflects the cells' fine internal structure and particulate matters. The photodiode receives these scattered light signals and converts them to electric pulses. According to the collected electrical pulse data, the two-dimensional distribution diagram of blood cell size and internal information can be obtained, which is called scattergram. In Figure 3.4.1-2, the abscissa reflects the information of the complexity of cells inside and the ordinate reflects the volume of the cell.

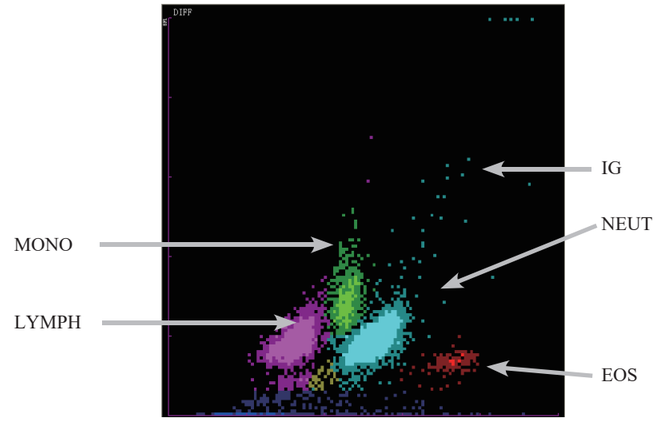


Figure 3.4.1-2

From DIFF channel, percentage of LYMPH, MONO, EOS, NEUT and IG of the WBC total count can be obtained.

3.4.2 WBC Counting (Coulter Principle)

When certain amount of blood cells react with a specific reagent, RBC and WBC excluding BASO are dissolved. With the reaction liquid driven by constant negative pressure, the cells will one by one pass through a small hole applied with constant current source. The number and height of pulses reflect the number and volume size of the cells. Principles are shown in Figure 3.4.2-1.

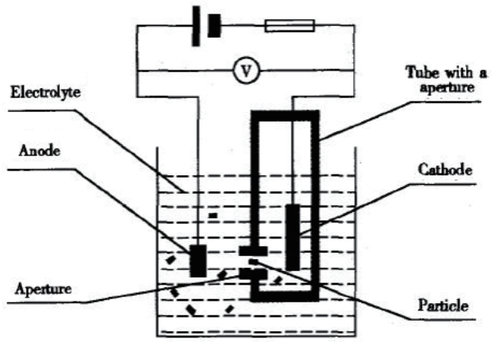


Figure 3.4.2-1

From the WBC histogram, WBC count, BASO count and the percentage of BASO of total amount of WBC can be obtained. Histogram is shown as Figure3.4.2-2.

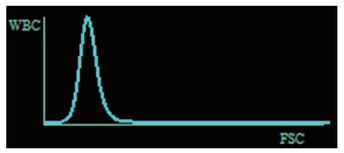


Figure 3.4.2-2

3.4.3 WBC Parameters

By analyzing the WBC histogram, the analyzer can compute White Blood Cell (WBC) count and basophile count (BASO#), and further get the basophile percent (BASO%). It can compute the neutrophile percent (NEUT%), the lymphocyte percent (LYMPH%), the monocyte percent (MONO%), the eosinophile percent (EO%) and the immature granulocytes percent (IG%) by analyzing the scattergrams and its area of neutrophile, lymphocyte, monocyte, eosinophile and immature granulocytes. Computing with the WBC count obtained from the WBC histogram, you can get the neutrophile count (NEUT #), the lymphocyte count (LYMPH#), the monocyte count (MONO#), the eosinophile count (EO#) ,the basophile count (BASO#) and the immature granulocytes count (IG #). The units of the cell count are 10^9 / L.

- WBC

WBC= Total number of particles on the WBC histogram except in the ghost

- NEUT%

$$NEUT\% = \frac{\text{Particles that fall in NEUT area from scattergram channel}}{\text{Total number of particles in the scattergram except in the ghost area}} \times 100\%$$

- NEUT#

$$NEUT\# = NEUT\% \times WBC$$

- LYMPH%

$$LYMPH\% = \frac{\text{Particles that fall in LYMPH area from scattergram channel}}{\text{Total number of particles in the scattergram except in the ghost area}} \times 100\%$$

- LYMPH#

$$LYMPH\# = LYMPH\% \times WBC$$

- MONO%

$$MONO\% = \frac{\text{Particles that fall in MONO area from scattergram channel}}{\text{Total number of particles in the scattergram except in the ghost area}} \times 100\%$$

- MONO#

$$MONO\# = MONO\% \times WBC$$

- EO%

$$EO\% = \frac{\text{Particles that fall in EO area from scattergram channel}}{\text{Total number of particles in the scattergram except in the ghost area}} \times 100\%$$

- EO#

$$EO\# = EO\% \times WBC$$

- BASO%

$$BASO\% = \frac{BASO\#}{WBC} \times 100\%$$

- BASO#

BASO#=Particle numbers that fall in the BASO area from WBC histogram

- IG%

$$IG\% = \frac{\text{Particles that fall in IG area from scattergram channel}}{\text{Total number of particles in the scattergram except in the ghost area}} \times 100\%$$

- IG#

$$IG\# = IG\% \times WBC$$

3.5 RBC/PLT Measurements

3.5.1 Coulter Principle

The analyzer uses the Coulter Principle to count the RBC/PLT. A certain amount of blood cells are injected into RBC reaction chamber after secondary
dilution. There is a small hole called detect hole in the RBC reaction chamber. The small hole is connected with positive and negative electrodes on the side and is charged with constant current source. Since the cell is a poor conductor, the resistance between the electrodes will change when the diluted cells pass
through the hole, thereby forming a pulse signal with the similar size of the

cell volume at both sides of the electrodes. When cells pass through the hole continuously, a series of pulses will be formed. Pulse number is consistent with the cell number, and the pulse height is related to the size of the cell. Principle is shown in Figure 3.5.1-1.
Pulse signal amplified by signal acquisition circuit is compared with the threshold of normal RBC /PLT volume range to calculate the count of cells which fall in the RBC/PLT range, so that we can classify the RBC and PLT and get their count. Abscissa represents the volume and the ordinate represents the relative count of cells so that RBC/PLT volume distribution histogram which is shown in Figure 3.5.1-1 can be obtained.

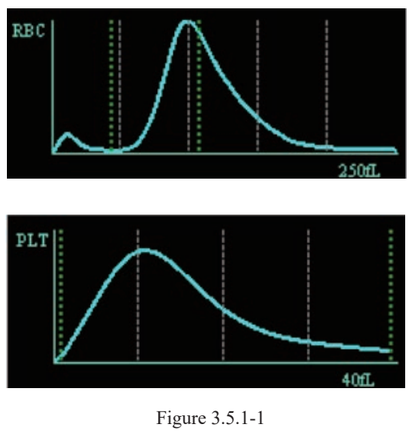


Figure 3.5.1-1

3.5.2 RBC Parameters

- RBC Count
  The RBC count is obtained by direct measuring corresponding electrical pulses numbers. Unit is 10^{12}/L.
- Hematocrit (unit: %)
  Hematocrit (HCT) was mesured according to the histogram of erythrocyte distribution, the unit is %.
- Mean Corpuscular Volume

$$MCV=\frac{HCT\times 10}{RBC}$$

- Mean Corpuscular Hemoglobin

$$MCH=\frac{HGB}{RBC}$$

- Mean Corpuscular Hemoglobin Concentration

$$MCHC=\frac{HGB}{HCT}\times 100$$

- RBC Distribution Width Coefficient of Variation
  RBC Distribution Width Coefficient of Variation (RDW-CV) is a coefficient of variation which is expressed in percentage and obtained from the RBC histogram.
- RBC Distribution Width Standard Deviation
  RBC Distribution Width Standard (RDW-SD) is the histogram width at 20%of the peak height on the histogram. Unit is fL. It is shown in Figure 3-6.

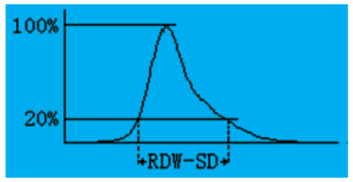


Figure 3.5.2-1 Diagram

3.5.3 PLT Parameters

- PLT Count
  The PLT count is obtained by direct measuring corresponding electrical pulses. Unit of 10^9/L.
- Mean Platelet Volume
  Compute Mean Platelet Volume (MPV) according to PLT histogram. Unit is fL.
- Platelet Distribution Width
  Platelet Distribution Width (PDW) is a geometric standard deviation which is obtained from the PLT histogram.
- Platelet Hematocrit
  The following equation can be used to compute the platelet hematocrit (PCT). Unit is %.

$$PCT=\frac{PLT\times MPV}{10000}$$

3.6 HGB Measurement

3.6.1 Colorimetry

In the colorimetric pool, after the diluted sample is added to the lysing reagent, red blood cells will dissolve and release hemoglobin, which unites with lysing reagent and becomes hemoglobin compounds. At one end of the colorimetric pool, illuminate the hemoglobin compounds with LED light emitted from a monochromatic light tube with 525nm wavelength; the other end receives transmission lights through phototube, and converts them to voltage signal after the optical intensity signal is amplified. By comparing it with the voltage obtained from the transmission light before the samples were added to the colorimetric pool (only diluents before), you can get the sample's hemoglobin concentration.

3.6.2 HGB Parameters

HGB is calculated by using the following equation, unit is g/L.

$$HGB=Constant\times Ln\left(\frac{Background\ Transmission\ Light}{Sample\ Transmission\ Light}\right)$$

Chapter 4 System Installation

4.1 Overview

The Automatic Hematology Analyzer has been checked strictly before leaving the factory and is packaged properly to avoid impact in the transportation. Please check packaging integrity carefully upon delivery. If there is any damage to the packaging, please inform the Post-sales Department of MACCURA or its local representative immediately.

Important	■ Unpacking or installation by personnel unauthorized or untrained by MACCURA may cause damage to the analyzer, so please do not open the package or install the analyzer without the presence of MACCURA authorized personnel. ■ If the device is not used over a long period of time, please execute the package shutdown program to empty reagents inside the device and wash it with deionized water. Device storage conditions should comply with the environmental requirements.

4.2 Installation Requirements

Make sure that the space, power, and environment meet the following requirements before installing the analyzer.

4.2.1 Space Requirements

In order to meet the equipment's maintenance space demands, and to ensure heat dissipation during usage and reagent pipe at the back of analyzer not be squeezed, the installation of the analyzer must meet the following space requirements:

- Reserved space between both side-doors and the walls should be ≥ 100 cm;
- Reserved space between rear panel and the wall should be ≥ 50 cm;
- Make sure that there is enough space for dilution, lysing reagent and waste barrels on the table or under the analyzer.
- Don't place the analyzer in a position where the switch is difficult to disconnect.

4.2.2 Power Requirements

Voltage	Power	Fuse Specifications	Frequency
AC 100 ~ 220V	≤ 240VA	250V T5A	50Hz/60Hz

Warning	■ Analyzer must be used in well-grounded conditions. ■ Device must use the fuse of specified standard. ■ Make sure that the voltage meets the requirements.

4.2.3 Environmental Requirements

- Environmental temperature: 15℃～ 30℃ ;
- Normal operating humidity range: relative humidity of 30%~85%;
- Atmospheric pressure:70kPa ～ 106kPa;
- Installation environment should be as free of dust, mechanical vibration, noise and strong power interference as possible;
- Do not place the device near strong electromagnetic interference sources, so as not to affect the normal operation of the device;
- Do not go near the brush-type motors, fluorescent lights flicker and the constantly switching electrical contact device;
- Device should avoid direct sunlight or being placed near a heat source;
- Keep the device ventilated;

Warning	■ Do not use analyzer in flammable or explosive environments, so as to avoid danger. ■ If the instrument is to be moved to a different location at a later time, please contact the local maccura representative.

4.2.4 EMC Requirements

The instrument requires favorable EMC environment, users should notice the following situations:

- Keep this instrument away from the high electromagnetic radiation, such as: dental drill, pacemaker and welding equipment etc.
- Keep this instrument away from the high power devices which start frequently, such as: refrigerater and centrifuge etc.
- Keep this instrument away from any magnetic field, such as radiology equipment.
- Do not connect more than one device on the wiring board for connecting this instrument.
- During the proceeding of this experiment, do not start other devices on the wiring board for connecting this instrument.
- Please ensure that the power outlet of this instrument is securely grounded, and do not use the non-standard power cord.

This instrument passed the electromagnetic compatibility testing, which satisfied with GB/T 18268.26-2010 measurement, control and the requirements of electromagnetic compatibility testing of electronic equipment for laboratory No.26 part: the special requirements IVD medical devices and GB/T 18268.1-2010 measurement, control and the requirements of electromagnetic compatibility testing of electronic equipment for laboratory No.1 part: normal requirements standard requirements.

The following use requirements during operating should be obeyed, or it may cause electromagnetic interference by other devices or decrease the resistance to electromagnetic interference of this instrument, even lose the basic function.

According to the design and testing for group I list A IN GB 4824-2013 for this instrument, on the family environment, this device may cause radio interference, which need adopt the prevention measurement.

The description for medical electrical equipment may affected by portable and mobile radio frequency communication equipment: the portable and mobile radio frequency communication equipment my affect the operation of this instrument, which guarantee the portable and mobile radio frequency communication equipment should have some space distance with this instrument, more specific requirements should follow the Table 4.

Warning 1: In addition to the equipment or system manufacturer as a spare part for internal components sold outside the transducer and cable, use the component which outside the provision, transducer and cable may lead to the increase of equipment or system launch or ths decrease of immunity. Warning 2: Equipment or system should not close or fold to use with other equipment, if it must close or fold to use, and then observe and verify the normal operation under this configuration.

Warning 3: Do not use this instrument beside the strong radiation source, or it mey interference the normal operation for this instrument.

Table 1

Instuction and the statement of manufacturer——Electromagnetic emission		
This Automatic Hematology Analyzer should use in the following specified electromagnetic environment, purchasers or users should use this instrument on this kind of electromagnetic environment.		
Emission experiment	Compliance	Electromagnetic environment——instruction
GB 4824 Radio frequency launch	Group 1	The automatic hematology analyzer only can use the RF energy for its internal functions.
GB 4824 Radio frequency launch	Class A	The automatic hematology analyzer could use for all the facility which not for family and not directly connected to the home for residential public low-voltage power supply network
GB 17625.1 Harmonic emission	Not applicable	
Voltage fluctuation/ Flashing GB 17625.2	Not applicable	

Table 2

Instruction and the statement of manufacturer——Electromagnetic immunity			
This Automatic Hematology Analyzer should use in the following specified electromagnetic environment, purchasers or users should use this instrument on this kind of electromagnetic environment.			
Immunity experiment	IEC 61326 Test level instruction	Achieve the electrical level	Electromagnetic environment ——Instruction
Electrostatic discharge GB/T 17626.2	±4 kV Contact discharge±8 kV Air discharge	±4 kV Contact discharge ±8 kV Air discharge	The ground should be woody, concrete or tile, if the ground covered by synthetic materials, the relative humidty should be at least 30%.
Electrical fast transient GB/T 17626.4	±1 kV pairs of power line	±1 kV pairs of power line	Network power supply should have the quality of typical commerce or hospital environment.
Surge GB/T 17626.5	±1 kV line to line±2 kV line to ground	±1 kV line to line±2 kV line to ground	Network power supply should have the quality of typical commerce or hospital environment.
Power input line voltage drops, immediately interrupt and voltage change GB/T 17626.11	0% UT, continually 1 cycle (100% drops at UT); 40% UT, continually 5 cycles (60% drops at UT); 70% UT, continually 25 cycles (30% drops at UT); 5% UT, continually 5 seconds (30% drops at UT).	0% UT, continually 1 cycle; 40% UT, continually 5 cycles; 70% UT, continually 25 cycles; 5% UT, continually 5 seconds.	Network power supply should have the quality of typical commerce or hospital environment. If the users of automatic hematology analyzer need continually operate it during interrupt period, and then recommend adopt UPS or battery supply.
Power frequency magnetic field （50/60Hz） GB/T 17626.8	3A/m	3A/m	If the work is abnormal, it is necessary to keep the automatic hematology analyzer away from power frequency magnetic field or install magnetic shielding. It should measure the power frequency magnetic field of anticipate installation site and meet the requirements of less than coincidentdet level.
Note: UT is the ac grid voltage before apply voltage.			

Table 3

Instruction and statement of manufacturer——Electromagnetic immunity			
The Automatic Hematology Analyzer anticipate be used in the following electromagnetic, purchasers and users should guarantee use this analyzer in this kind of electromagnetic environment.			
Immunity test	IEC 61326 Test electrical level	Achieve the electrical level	Electromagnetic environment——Instruction
Radio-frequency conduction GB/T 17626.6	3V(Effective value) 150 kHz ~ 80 MHz Effective value	3V(Effective value)	Portable and mobile radio frequency communication equipment should not closer than recommended isolation distance to the any parts of automatic hematology analyzer, which include cable, the calculation of distance should use the corresponding fomula for transmitter frequency. Recommended isolation distance $d=1.2\sqrt{P}$ $d=1.2\sqrt{P}$ 80 MHz ~ 800 MHz $d=2.3\sqrt{P}$ 800 MHz ~ 2.0 GHz In the formula: P——The maximum rated output power of the transmitter provided by the transmitter manufacturer, which use W as unit; d—— d——Recommended isolation distance, which use m as unit. Field for fixed radio frequency transmitter measured by electromagnetic place a, which each frequency range b should less than achieve the electrical level. There may be interference near the device where has already marked the following symbol.
Radiofrequency radiation GB/T 17626.3	3 V/m 80 MHz ~ 2.0 GHz	3 V/m	
Note 1: the formula for higher frequency should be adopted between 80 MHz and 800MHz. Note 2: These inductions may be not suitable for all situations. And the electromagnetic transmission may effected by construction, substance and the absorption and reflection of human body.			
a. Fixed transmitters, such as, radio telephone (honeycomb/wireless) and ground mobile radio base station, amateur radio, AM/FM radio and TV broadcast etc, the field cannot be accurately predicted by theory. In order to assessing the electromagnetic environment of fixed radio frequency transmitter, which should considered the assessment for electromagnetic site. If the field measured by automatic hematology analyzer higher than the following RF compliance level, which should measure the automatic heatology analyzer to verify its normal working. If it detect the unormal function, so it is necessary to supplement measure, such as readjust the direction or site for automatic hematology analyzer. b. The field should less than 3 V/m between 150 kHz and 80MHz.			

Table 4

Recommended isolation between portable and mobile radio frequency communication equipment and automatic hematology analyzer The automatic hematology analyzer anticipate use in radioactive radiation harassment controlled electromagnetic environment. According to the maximum power output for communication equipment, the purchasers or users for automatic hematology analyzer could use the shortest distance between maintain portable and mobile radio frequency communication equipment (transmitter) and automatic hematology analyzer to prevent from electromagnetic interference.			
The maximum power output for transmitter (W)	The isolation distance for the corresponding transmitters/m		
	150 kHz ~ 80 MHz $d=1.2\sqrt{P}$	80 MHz ~ 800 MHz $d=1.2\sqrt{P}$	800 MHz ~ 2.0 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 the maximum power output for transmitter which unlist in the above table, recommend isolation distance as d and unit as m, which could use the formula in the corresponding transmitter frequency list, P is the maximum power output of transmitter which supplied by transmitter manufacturer, which use W as unit. Note 1: the formula for higher frequency should be adopted between 80 MHz and 800MHz. Note 2: These inductions may be not suitable for all situations. And the electromagnetic transmission may effected by construction, substance and the absorption and reflection of human body.			

4.3 Analyzer Connection

Maccura authorized personnel should complete the following connections when installing the analyzer.

4.3.1 Pipeline Connection

Warning	■ The handling of reagents, waste fluid, and waste samples, etc. should comply with the local and national regulations about the discharging and handling of bio-infectious materials like reagents, waste fluid, etc. ■ Reagents may irritate eok, skin and mucous membranes. The operator should comply with laboratory safe operation regulations and wear personal protective equipment (such as laboratory protective clothing, gloves, etc.) when using or touching related items of reagents. ■ Once reagent touches the skin, rinse with plenty of water immediately and seek medical treatment if necessary. ■ Once reagent touches the eok, rinse with plenty of water and seek medical treatment immediately.
Important	■ Do not place the reagents or other liquids on top of the analyzer.

Analyzer tubing connections is shown as figure 4.3.1-1.

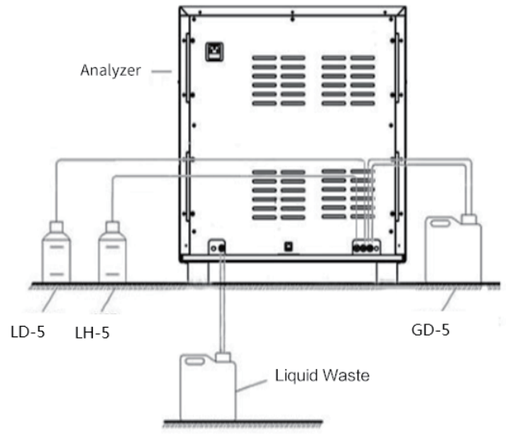


Figure 4.3.1-1

4.3.2 Optional Equipment Connection

The connection of the analyzer and the optional equipment is shown in figure 4.3.2-1. Make sure the connections are solid and reliable.

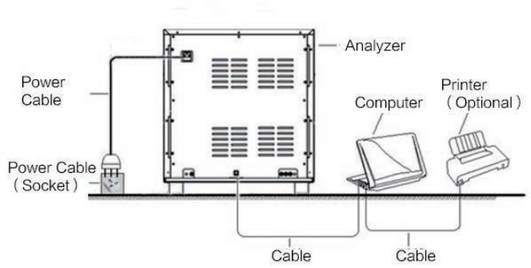


Figure 4.3.2-1

4.4 Software operating environment

- Hardware Configuration：
  CPU：Intel Celeron J3060 1.6G 2C
  Memory: 4GB DDR3 1600 SoDIMM
  Peripherals: printer (optional), mouse, keyboard, Hand-held bar code scanner

- Software configuration：
  32 bit Windows operating system (Window 7 or 10),
  .Net FrameWork 4.0 environment, MySQL Server 5.7 database, Office software

- Network: B/S structure, LAN, bandwidth: 100Mbs

Chapter 5 Basic Settings

5.1 Overview

Analyzer has been initialized at the factory settings before leaving the factory, so parameters and reference values are at default.

Users can reset some parameters depending on the actual need.

5.2 Setting Item

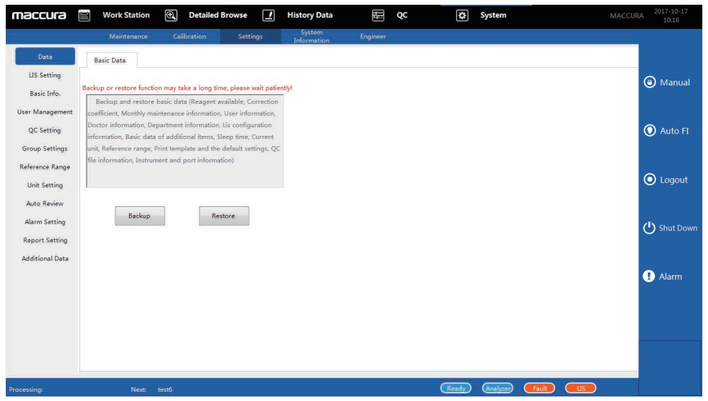


Figure 5.2-1

5.2.1 Report settings

Click “system” —“setting” —“report setting”, and then enter into report setting interface, please follow as picture 5.2.1-1.

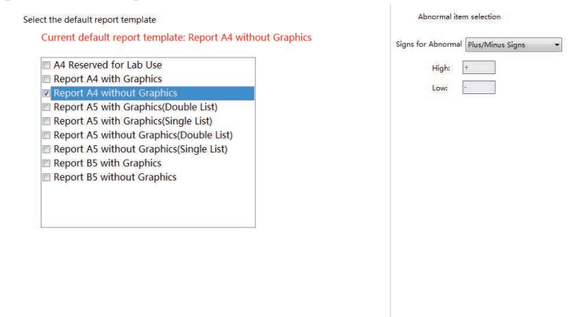


Figure 5.2.1-2

- Default Template Setting
  It can choose software which already has have worksheet template, select it and click “save”.
- Report settings

→ Signature
Non-automatic signature: no information about the inspector and reviewer, the report shall be manually signed by the inspector and reviewer after printed.

→ Abnormal Results Prompt Choosing
“↑” “↓” and “+” “-” can be selected to prompt that the result exceeds the reference range.

5.2.2 Sample Generating Method

After the program starts, user can click “Setting”-“General”-“Sample scanning” to set the sample generating method (matching method) as shown in Figure 5.2.2-1.

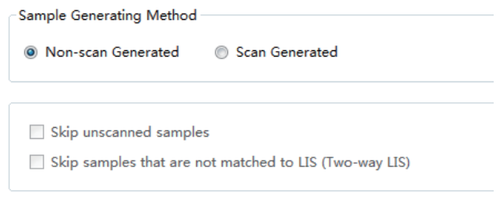


Figure 5.2.2-1

- Sample Generating Method

→ Non-scanning Generating Method
After checking the work sheet mode, measuring samples’ sample number source is the registered work sheet sample or automatically generated sample.

→ Scanning Generating Method
After checking scanning generating mode, measuring samples’ sample number source is the sample number obtained from scanning by the barcode scanner.

Important	■ Only when the device is in ready status can the sample matching method be modified.

5.2.3 Browse Setting

It is used to set the display method (2D or 3D) of the detailed browsing scattergram. User can select 2D or 3D scattergram by clicking “Setting”- “General”-“Browse Setting”. Click “Save” to save current settings as shown in Figure 5.2.3-1.

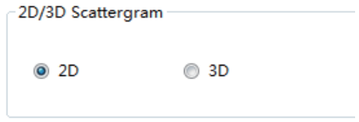


Figure 5.2.3-1

5.2.4 Reference Range Setting

After user starts the program, click “System”-“Setting”-“Reference Range” to set the reference range of the result, as shown in Figure 5.2.4-1.

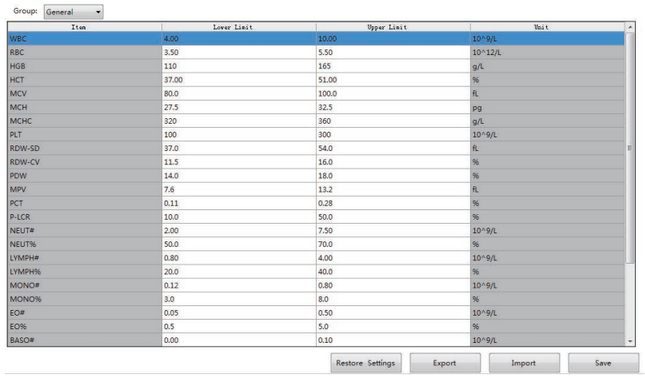


Figure 5.2.4-1

Click the item name, the item will be indicated by highlight, the upper and lower limit of current setting reference value will be indicated on the right side, modify the numbers in “upper limit” and “lower limit” input box separately, click and move to next item after finishing modification. And then click “save” button to
reserve after finishing all the settings.

- Group
  Click “group“drop down box, which could modify the different reference value group, system will supply 5 default groups and 5 custom groups, and also you could click “newly increase” button to add mulitiple custom groups.

- Restore to Default
  Click “Restore” and the system will restore the references value to factory setting.

- Restore Settings
  Click the "Restore Settings" button, the system will save the current reference value to the factory settings.
- Import
  Click “Import” and the reference values file selection window pops out. Select the existing “.xml” file format as reference values file, as shown in figure 5.2.4-2

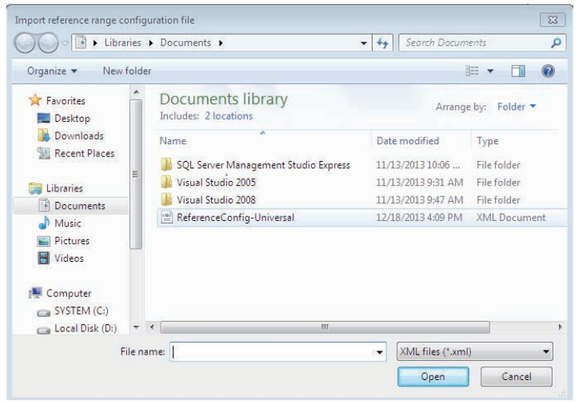


Figure 5.2.4-2

- Export
  Click“Export”and the saving interface pops out, as shown in figure 5.2.4-3.

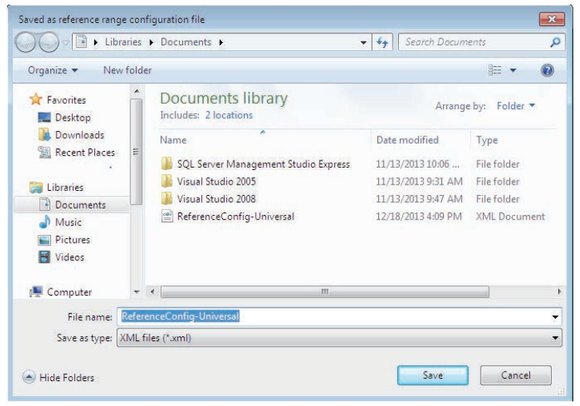


Figure 5.2.4-3

- Save
  Click “Save” to save the current modifications and exit reference value interface.

5.2.5 Reference Group Setting

After user start the procedures, click “system” —“settings” —“group settings” to proceed the classification settings of reference groups, please follow as picture 5.2.5-1.

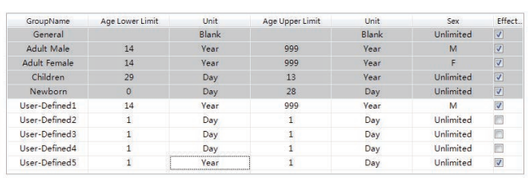


Figure 5.2.5-1

Important	■ The default groups cannot be modified. ■ When default groups are the same with the user-defined groups. User-defined reference value enjoys priority.

■ Enable User-defined Group

Click the “Effective” radio button, and select to enable the user-defined group.

■ User-defined Group Modification

Modify user-defined group age, unit, and sex.

Double click age to modify;

Double click age unit to choose the age unit of the group, with three kinds of “Year”, “Month” and “Day” available;

Double click “Sex” to choose the sex of the group, with three kinds of “Unlimited”, “Male” and “Female” available.

5.2.6 Alarm Condition Setting

Click “system” —“settings” —“IP alarm settings”, which could modify IP alarm threshold, please follow as picture 5.2.6-1.

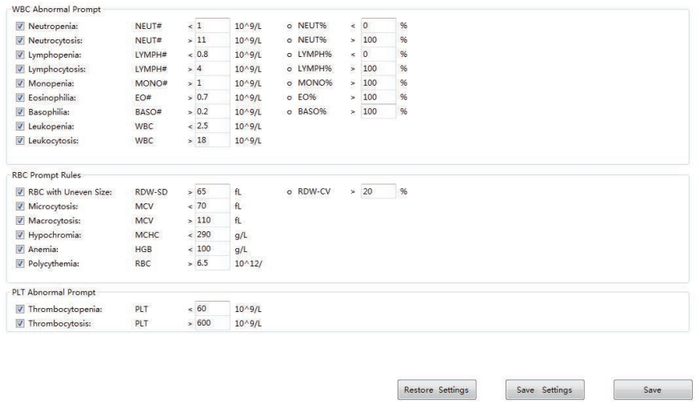


Figure 5.2.6-1

→ Save

Click “save”, save current modification and exit current interface. → Restore to Factory Setting

Click “Restore” to restore the IP alarm threshold value to factory default setting.

5.2.7 User Management

Click “system” —“settings” —“user management”, which could enter into user management interface, please follow as picture 5.2.7-1.

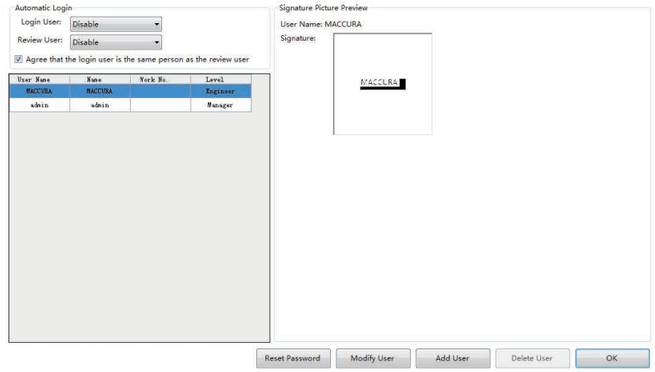


Figure 5.2.7-1

■ Auto Login

The account for automatically log in could be chosen in the automatically log in interface.

“Current account” indicate the account which have already set auto login. “Set account” could select the account which need auto login.

Important	■ Low-privileged account cannot set high-privileged as automatic login account. ■ When “User Setting” is disabled, it means that there is no automatic login account and the account name and password must be entered manually when starting the software.

■ Reset password

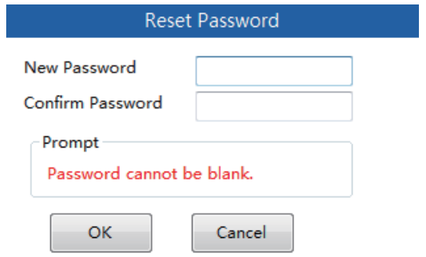


Figure 5.2.7-2

Select the user and click“Reset”to enter the new password twice. Click“OK”to save the new password.

■ Modify User

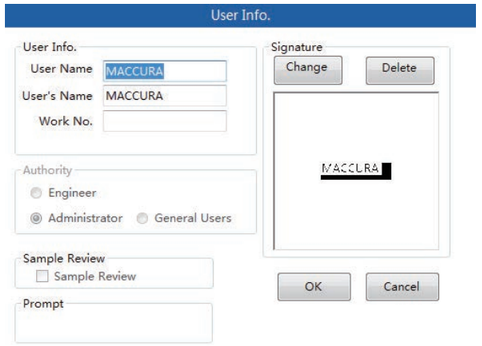


Figure 5.2.7-3

Select the user, click “Modify User” to enter user modification interface.

■ Add User

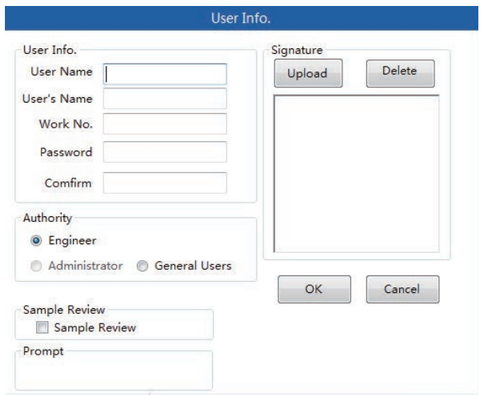


Figure 5.2.7-4

Click “Add User” to enter user creation interface.

Important	■ The first installed user account should be set up by engineer, and the general user can be set up by an administrator account or an engineer account.

“User Name” is the account name entered when logging into the software; “Authority” is the new user’s level;
“Sample Review” is used to determine whether the new user has a sample review authority. If it is selected then the user has review authority.

■ Delete User
Click “Delete”, and the following box will pop out. Click “OK” to delete the user and exit the interface;

Click “Cancel” to exit this interface without deleting the user.

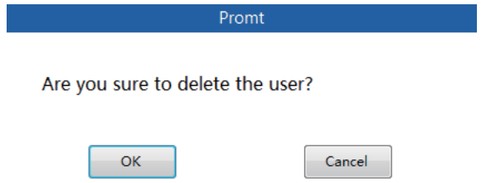


Figure 5.2.7-5

■ OK
Click “OK” to save the current modification and exit the delete user interface.

■ Cancel
Click “Cancel” will not save the current modification and exit the delete user interface.

5.2.8 Operation Log Management

Click “system” —“maintenance” —“Log” to enter operation log management interface, please follow as picture 5.2.8-1.

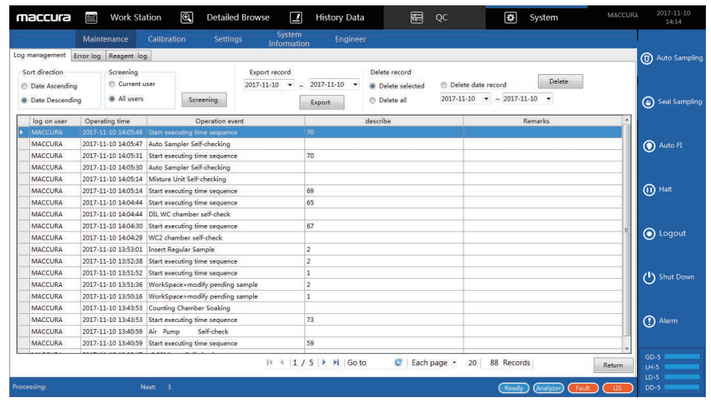


Figure 5.2.8-1

■ Filter
→ Operation Date Ascending or Operation Date Descending can be selected in “Ranking Direction”.
→ Current User or All users can be selected in “Filter Requirements”.

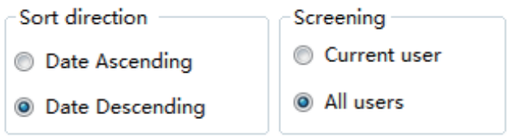


Figure 5.2.8-2

■ Export

"Export Records" can select the time period that needs exporting. Click "Export" and the file saving window will be pop out.

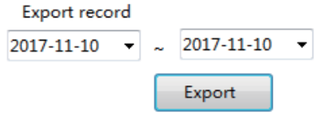


Figure 5.2.8-3

■ Delete

→"Delete Selected Record(s)" can precisely delete the selected record(s); →"Delete Record(s) within a Specified Time Period" can delete record(s) within the specified time period in bulk;

→"Delete All" can delete all operation records;

→ Click "delete" and the deletion confirmation prompt box will pop out, click OK to delete corresponding record(s).

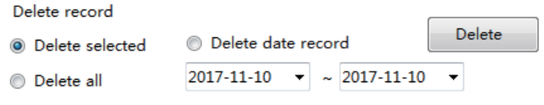


Figure 5.2.8-4

5.2.9 LIS settings

Click "system" —"settings" —"LIS settings"to enter LIS settings interface, please follow as picture 5.2.9-1.

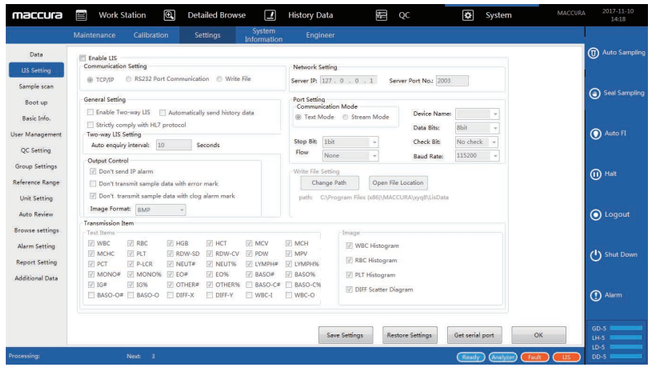


Figure 5.2.9-1

■ LIS function

→ Server IP: input the IP address of the LIS server;

→ Server port number: input the port number provided by LIS server; → Enable LIS: selected means enabling LIS function

→ Enable two-way LIS: selected means to obtain test mode and patient information from the server;

→ Automatically send history data: selected means to send unsent result information in the history data automatically;

→ Automatic query interval: after enabling two-way LIS, automatic query interval can be set;

→ Send images: whether WBC, RBC, PLT histogram, and DIFF scatter plot are included in the packet, selected by default;

→ Send IP alarm item: whether the IP alarm item is included in the packet, selected by default.

→ Strict compliance with HL7 agreement: LIS data packets in strict accordance with the HL7 header format, the default is not selected.

5.2.10 QC

Click "system" —"settings" —"QC setting"to enter the QC setting interface, please follow as picture 5.2.10-1.

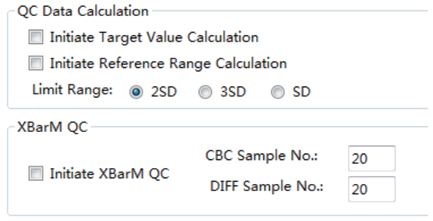


Figure 5.2.10-1

■ QC data calculation

There are two calculation methods to be chosen, such as"start the target value calculation" and "start the reference value calculation", and it can also select all or unselect all.

Limit range can be selected from 2SD, 3SD and SD, only a single choice.

■ X-M QC

Select it and then start the X-M QC.

■ OK

Click "ok", and then save the current modification.

■ Restore to factory setting

Click "Restore factory settings" button, and the parameter of current interface will be reset to the initial value.

5.2.11 Additional data item

Click "system" —"settings" —"additional data item"to enter into additional data item settings interface, please follow as picture 5.2.11-1.

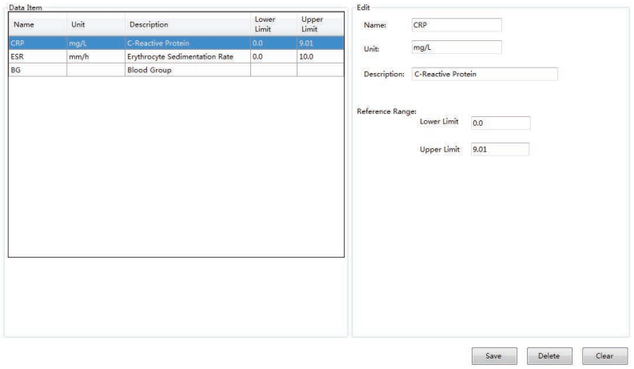


Figure 5.2.11-1

- Add data items
  Randomly select an original data item, modify the name, units, description and reference ranges, and then click “save” button.
- Delete data item
  Select the data item which need to be deleted, and then click “delete” button.

- Data item modification
  Select the data item which need to be modified, and then modify it.

Important	■ The name cannot be changed during data item modification, or it will be regarded as newly increase data item.

5.2.12 Unit settings

Click “system” —“settings” —“unit setting”, the unit setting will be poped up, please follow as picture 5.2.12-1.

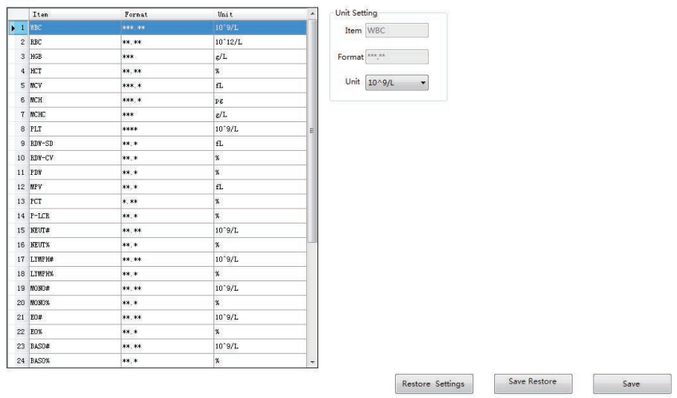


Figure 5.2.12-1

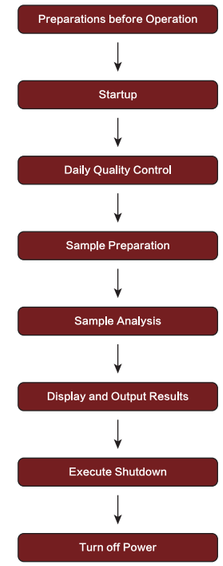
- Save
  Click “save” button, which could save the modification for units.
- Restore factory settings
  Click “Restore” button, and the parameter of current interface will reset to the initial value.

Chapter 6 Daily Operation

6.1 Overview

System contains a mainframe for testing, a set of supporting F 580 software for measurement, a computer (optional) for data processing, and a printer (optional).

This chapter introduces the daily operation of the instrument from startup to shutdown. This instrument supports automatic sampling and closed sampling mode, the automatic sampling supports 2 mesure modes: CBC+DIFF whole blood and CBC whole blood, closed sampling supports 4 measure modes: CBC+DIFF whole blood, CBC whole blood, CBC +DIFF pre-dilution and CBC pre-dilution. The daily operation flow is as follows:



Preparations before Operation

Check the following to ensure that the system can operate normally before turning on the device.

- Samples, calibrator, control, and waste liquid, etc. are potentially biological infectious. The operator should comply with laboratory safe operation requirements and wear personal protective equipment (such as laboratory protective clothing, gloves, etc.).
- This instrument within the liquid pipeline, it is recommended to check for leakage during each self-test run, if so, immediately shut down and contact post-sale department of our company.
- In order to making sure the instrument is in safety status before use, please confirm whether the power supply, grounding conditions, waste discharge piping, etc. meet the requirements of this user manual or not.

Warning	■ The handling of reagent, waste liquid, and waste samples, etc. should comply with the local and national regulations on bio-infectious materials like reagents and waste fluid, etc.

Do the following check before turning on the instrument:

1. Check the waste barrel
   Make sure that the waste bucket is empty before the test each day.
2. Check the reagents and connecting pipeline

■ There are some differences between reagent amounts and analysis modes. Make sure that there is adequate amount of reagent for usage before startup every day, and prepare additional reagents for replacement.
During the analysis, the instrument will stop automatically if the reagent is used up.
If it happens, replace the used reagent.
After the reagent has been replaced, start the analysis again.
Make sure that the pipelines connected with the reagent bottle are not folded or twisted, etc.Make sure the power cord is in contact with the socket.

Reagent consumption is as Table 6.1-1 shows.

Reagent Name	Single Sample Test (or other operate) Consumption	
	CBC+DIFF	CBC
GD-5 Diluent	≤ 32mL	≤ 26mL
LH-5 Lysing Reagent	≤ 0.38mL	≤ 0.38mL
LD-5 Lysing Reagent	≤ 1.2mL	0
DD-5 Fluorescent Dye	≤ 30uL	0
CC-5 Cleaning Fluid	≤ 2mL/ Maintenance	

Table 6.1-1

3. Check printer (Optional)
   Check whether printer paper is enough and whether power connection with computer is well.
4. Check the network communication connection for instrument and computer is normal or not.

6.2 Startup

Start the computer and open the F 580 software, switch to “on” position on the right of the Analyzer mainframe. After power on, the indicator light will on light.

Important	■ You can either start F 580 software first or the Analyzer mainframe first. There is no required order.

When the mainframe and the F 580 software have been started, both of them will connect automatically. The system will perform startup sequence after successful connection, including version checking, device cleaning, time sequencing loading and background checking.
When the time sequence of the device cleaning is completed successfully, the instrument will automatically enter the background checking. If the first time is not passed, it will be executed second times. The temperature detection is carried out after the background checking.
If startup fails, the buzzer will give off alarm and the software displays the warning dialog box. User can operate according to the instructions of the dialog box. If the problem is still unresolved, please contact to maccura customer service.

6.3 Quality control

Before sample analysis, the device requires daily QC to ensure reliable results. See Chapter 10 Quality Control for detailed QC methods.

6.4 Analysis mode

This instrument only support the following 2 analysis modes:
Automatic sampling mode: in this operation mode, the operator put the samples into the sample rack, the analyzer will mix and perform the test with punture sampling in order automatically.
Closed sampling mode: in this operating mode, the operator mix the samples manually and then put them in closed sampling position, the analyzer will perform the test with puncture sampling.

6.5 Sample Preparation

	■ Samples, calibrator, control, and waste liquid, etc. is potentially biological infectious. The operator should comply with laboratory safe operation requirements and wear personal protective equipment (such as laboratory protective clothing, gloves, etc.). ■ Do not contact patient's blood sample directly.

Important	■ All performance results in this user manual were obtained using EDTA anticoagulants in whole blood samples. The use of other anticoagulants will affect the results. ■ Please ensure this instrument have no faults before quality control.

6.6 Work List Information Registration

If the match method for sample is “non-scan generation” match method, worksheet sample need to be registered before measure them. Open software in “work station” interface, please follow as picture 6.6-1.

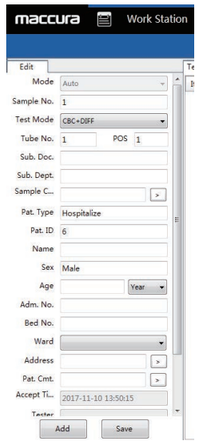


Figure 6.6-1

Click “add” button, edit sample information. Sampling mode(automatic or closed, sample No. (after clicking “add”, it will be automatically generated and can be modified), the test mode is required to import, the sample rack number and the position number need to be entered in automatic sampling mode(after clicking “add”, it will be automatically generated and can be modified). The information of the patient, the department and the inspection doctor are all optional (the information can be modified before or after the measurement). After the sample is edited, click the "save" button. After successful saving, it will be displayed on the "sample to be tested" sheet on the right.

Important	■ When registering work sheet samples, test tube rack number and sample number should be composed in order for the software to identify the next to be tested sample conveniently during measurement. Discontinuous sample numbers or disorder may be unidentifiable for the software. ■ Closed sampling match with sample number, for example, when the current measuring worksheet sample number is “W1”, the next automatically matched worksheet sample number is“W2”; when the test worksheet do not have“W2”, match is failed, user need manually set the next worksheet sample or use the automatically generated sample after finishing measure procedure. ■ “BLANKCHECK”, “CORRECTION” and the sample number start from “QC-“is corresponding background test sample, calibration sample and QC sample separately. Therefore, register worksheet sample cannot use these three special sample number.

6.7 Whole Blood Samples

The preparation method of whole blood samples:

1. EDTA-K_2, EDTA-K_2, EDTA-Na_2(1.5 ~ 2.2mg/mL blood) Anticoagulation vacuum blood collection tube is used to collect vein blood samples .
2. After collection, immediately shake the collection tube upside down several times to mix the blood with anticoagulant thoroughly.

Important	■ In manual whole blood mode, blood sample must be more than 1ml. ■ The samples needed for WBC classification and PLT count should be stored at room temperature and analyzed within 4 hours after collection. If not, please store it within 2℃ -8℃freezer, until can begin analysis. ■ If the results of WBC classification, PLT count and MCV are not needed, the samples can be stored in the refrigerator with the temperature of 2 ℃ ~ 8 ℃ for 24 hours. ■ The frozen sample should be placed in the room temperature for 15 minutes to 30 minutes before analysis, and then lightly shake samples 10 times. ■ Capillary blood is collected into a microcatheter to which anticoagulant was added. ■ After standing for some time, the sample needs to be re-mixed before be analysis.

6.8 Pre-diluted sample Pre-diluted

sample preparation methods:

1. Click “auto FI” button in software, please follow as picture 6.8-1.

Figure 6.8-1

2. It will pop up the automatic injection dialog box, please follow as picture 6.8-2.

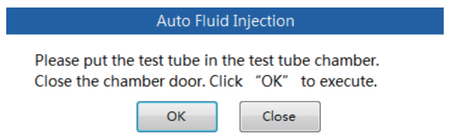


Figure 6.8-2

3. Put the tube under manual sampling position, click “ok”button, and then the instrument will automatically perform the automatic injection procedure, please follow as picture 6.8-3.

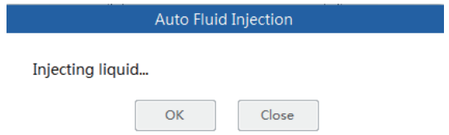


Figure 6.8-3

4. After the automatic injection is completed, click the "exit" button to exit the automatic injection.
5. Manually mix the 20μL peripheral blood and 200μL diluent outside the instrument.

6. After the sample is mixed thoroughly, open the lid and place the mixed samples under the aspiration pipette carefully as shown in 6.8-4. Press the start button, and the pipette will draw about 91.5ul diluted sample for analyzing, and display the results of the analysis which has been multiplied corresponding times.

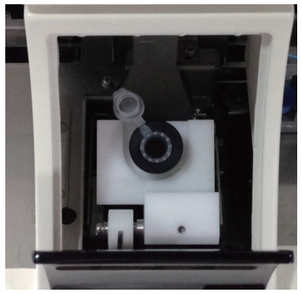
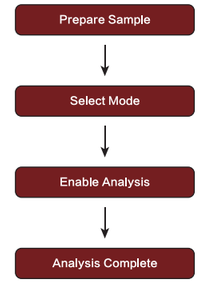


Figure 6.8-4

Important	■ The mixture of capillary blood and dilution should be placed 3 minutes before the test. ■ Make sure that the capillary blood samples are tested within 30 minutes after dilution. ■ Laboratory should evaluate the stability of the test results under pre-dilution mode according to its the number of samples, sample collection methods and technology.

6.9 Automatic sampling analysis

The operation procedures are as follows:



1. Place the test tube that needs measuring on the test tube rack in order, and place the test tube racks to the right platform of the automatic sampler in the device.

2. In ready status, set the first to be tested sample information area on the right side of the screen (as shown in Figure 6.9-1). Select “Automatic” for sampling method, and set the first to be tested sample’s measuring mode and sample information.

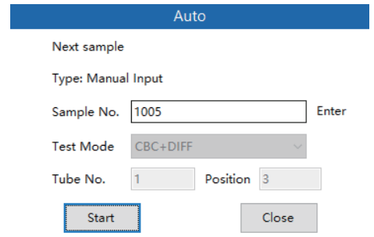


Figure 6.9-1

3. After input, click the automatic sampling measure button on the device or in the software.

4. The device starts measurement, measuring the samples on the test tube racks one by one.
5. When all samples are measured, take out the measured test tube racks from the left platform of the automatic sampler.

- Under non-scanning method, the set sample information is the first sample's information, and the following sample information automatically matches during measurement. For example, if the first sample is a work sheet sample, then the following sample matches from the work sheet sample. The first sample is automatically generated, the following sample is generated base on the previous measuring sample.

- If the input sample number is from work sheet, the software will automatically match the measuring mode, test tube rack number and position number. If it is not a work sheet sample, user also has to input measuring mode, sample number, test tube rack number and position number (1-10). Under scanning match method, only measuring mode needs setting.

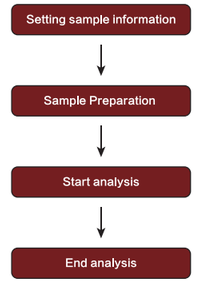
Important

- When using multiple test tube continuous measurements for work sheet samples, please make sure the test tube rack numbers are continuous. If the registered test tube rack numbers are not continuous (for example the registered test tube rack numbers are 1, 3, 4 with no 2), the samples on test tube 3 and 4 will not be measured because when test tube rack 1 measurements are complete, test tube rack 2 cannot be found. The software is used to generate automatically sample information after test tube rack 1 completes measurements.

- The measuring mode of the samples on the same test tube rack must be the same. The measuring mode of the samples of the same batch should also be the same.
- When sample information is automatically generated, sample numbers and test tube rack numbers are generated based on the previous sample number +1.
- Scanning match method requires the support of device scanning units. If the sample number scanning fails, sample measurement will not stop, the sample number failed scanning would be replaced by "SCANERROR" (can be modified after measurement).

6.10 Closed sampling analysis Operation

workflow as follows:



Specific operation steps are as follows:

1. After well prepared, sample information need to be set by "closed sampling" button on the right of software menu area (please follow as picture 6.10-1).

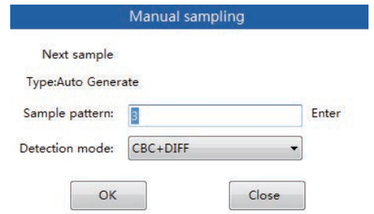


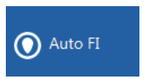
Figure 6.10-1

2. Shake the tube firstly, open the sample gate, place the totally mixed blood into the closed injection device and close the gate.
3. Click "closed sampling" button on the instrument to start measurement.
4. After finishing sucking blood, please take out the sample from the closed injection device.

Important	■ After the sample measurement begins, the matching method of the sample is based on the first sample. If under work sheet match mode, automatically match the next samole according to the order of matching a sample (such as single sample of 1 and 2,1 after the start of the 2 automatic measurement, as the default sample, if not registered 2, matching failure); if the automatic matching method, with +1 type production a sample (such as the current measurement of the sample number is "S1", is a default manual sampling sample number for the "S2"). In the way of scanning matching, the sample number is not generated. It is necessary for users to manually input barcode (barcode number as sample number). No barcode is allowed to be measured. ■ Closed sample measurement support continual mesurement, after finishing the blood absorption of the previous sample, take out the sample, and then put the second sample into manual sampling device and press the measurement button. When continually measuring, the measurement mode of the samples must be consistent. ■ When it registers the worksheet sample of manual sample, sample No. should be continuous, which could be easy to automatically match next worksheet sample during measurement procedure, which could reduce manual setting and improve work efficiency.

6.11 Insert Measurement (Emergency)

During automatic sampling, if there is a need to insert an emergent sample (sealed sampling method), follow the following method to operate:



1. Click “Pause” on the right side of the software, and the device will stop measurement after the current sample measurement is complete.
2. After the device stops, set the inserted sample’s information in the “Next” area at the right side of the software. Select “Sealed” for sampling method and input the inserted sample’s number and measuring mode.
3. Shake the test tube and press “Door”button to open the sealed sampling cabin door. Place the thoroughly mixed blood in the cabin and close the cabin door.
4. Click the sealed sampling measurement button on the device or in the software to start the measurement.
5. The device starts measurement.

Important	■ The operations from Step 2 are the same as those of the sealed sampling measurement.

6.12 Automatic Sampling Measurement Restoration

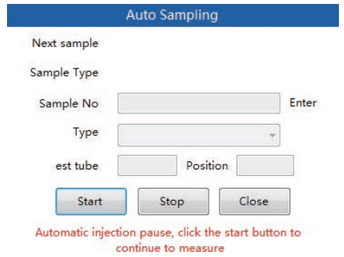


Figure 6.12-1

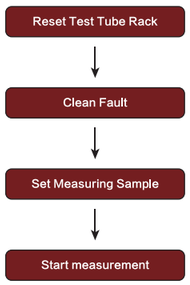
When measurement is interrupted during automatic sampling due to emergent sample insertion, automatic sampling can be restored according to the following operations.

1. When the device is in ready status, click the “automatic sampling”button in the menu area on the right side of the sofeware.
2. Click the automatic sampling measurement button on the device or in the software.
3. The device starts and resumes measuring where it was stopped.
4. In the suspended state, the operation can be canceled by pressing the “Halt”button.

Important	■ During automatic sampling measurement, if stopping faults occur (such as HGB voltage abnormal, jewel hole clogging, etc.), the device will automatically stop after the current sample (samples already at the puncture position) measurement is complete. At this time user should clear the fault (see fault handling chapter). After the fault is cleared, click automatic sampling measurement button to continue.

6.13 Automatic Sampling Measurement Restoration

During automatic sampling, if machine-halt fault occurs, the device will stop measuring. After the device stops, restore measurement according to the following steps:



Specific operation procedures are as follows:

1. Check whether the test tube rack is removed when the device stops. If not, open the cabin lid and check whether there are test tubes on the mechanical clamp. If there are, take the test tube from the clamp and replace it to the corresponding test tube rack.

2. Pull out the test tube rack that has been stopped measuring (push from right to left).

3. Place the test tube rack that has been stopped measuring and the subsequent test tube racks in order to the initial position at the right platform.
4. Execute fault clearing operation (see fault handling chapter).
5. After the fault is cleared, set sample measuring information (input the next sample's position information according to the prompt texts in red) in the "Next" area at the right side of the software. Input sample number, measuring mode, test tube rack number and position numbers as shown in Figure 6.13-1 (resume measurement from the second position).
6. Click the automatic sampling measurement button on the device or in the software.

7. The device starts measurement.

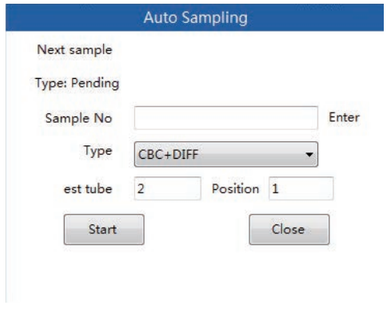


Figure 6.13-1

Important	■ Machine-halt condition is divided to immediate halt and delayed halt (halt after the current sample measurement is complete). ■ If the input sample comes from work sheet, the software will automatically fill in the measuring mode and test tube rack information. If the match method is scanning method, sample number does not need inputting. ■ Step 5 can be skipped. After clearing the fault, clicking the automatic sampling measurement button can also start measurement. The system automatically generates the first to be tested sample's information according to the measurement before the halt. When new test tube is to be measured after the halt, sample information must be set manually. ■ When executing the first step, after opening the cabin lid, if user finds that the aspiration pipette is inserted in the test tube and the test tube rack cannot be removed, he/she can conduct a "Liquid Path Initializing" to restore the aspiration pipette and then remove the test tube rack. Please refer to Maintenance chapter for the use of "Liquid Path Initialization".

6.14 Results View

After finishing sample analysis, the results could be seen in "tested sample" list in the working interface, please follow as picture 6.14-1.

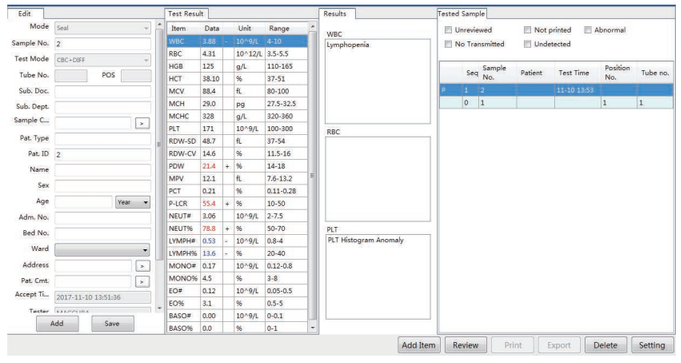


Figure 6.14-1

After clicking the sample, the analysis results are displayed in the middle area. If we need to modify the information of the tested samples and edit directly in the left edit window, we must input the patient's ID information when we need to input the patient information. Sample ananlysis results could also be checked in history data and detailed browse function, more specific information could be seen in results examine chapter.

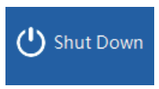
6.15 Shutdown and exit procedure

If the device is in continuous operation, shutdown operation must be performed at least every day after the end of the analysis or every 24h.
The tubes, detection and analysis components of the device will be cleaned when the device performs shutdown operation.

Important	■ To ensure reliable and stable performance of the analyzer, please make sure the following steps are followed to perform shutdown process.

Shutdown operation steps:

1. When the analyzer is ready, click the Shut Down button in the task bar of the system function.



2. The screen pops up the prompt window as picture 6.15-1.

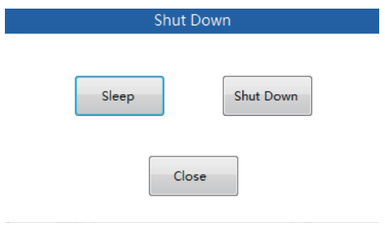


Figure 6.15-1

3. Click“shut down”button,“Power off”interface will pop out as picture 6.15-2 shows.

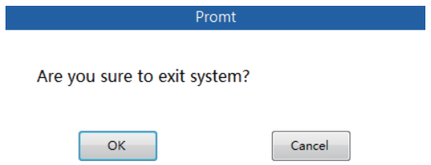


Figure 6.15-2

4. Click "OK" button, the analyzer will perform the shutdown process. After the shutdown process is completed, the system prompt will pop out, as shown in figure 6.15-3.

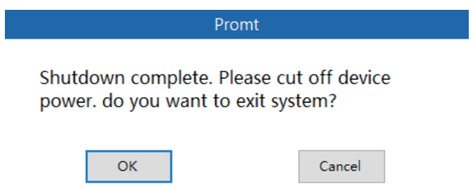


Figure 6.15-3

5. Click “OK” to exit the system software; Click “Cancel”, the system software will continue to operate offline.
6. Turn off the power switch on the right of the analyzer.
7. Empty the waste bucket, and handle the waste solution and waste samples properly.

	■ Samples, calibrator, control, and waste liquid, etc. is potentially biological infectious. The operator should comply with laboratory safe operation requirements and wear personal protective equipment (such as laboratory protective clothing, gloves, etc.).
Important	■ After the device is power off, user can still use the F 560 software’s functions of results checking, results printing and other non-interactive features with the host machine. ■ If it needs to operate software continually after shutdown procedure, next time you start the machine, be sure to restart the software.

Chapter 7 work station

7.1 Overview

Click “work station” button to open the work station interface for sample registration, result view, etc., as shown in figure 7.1-1.

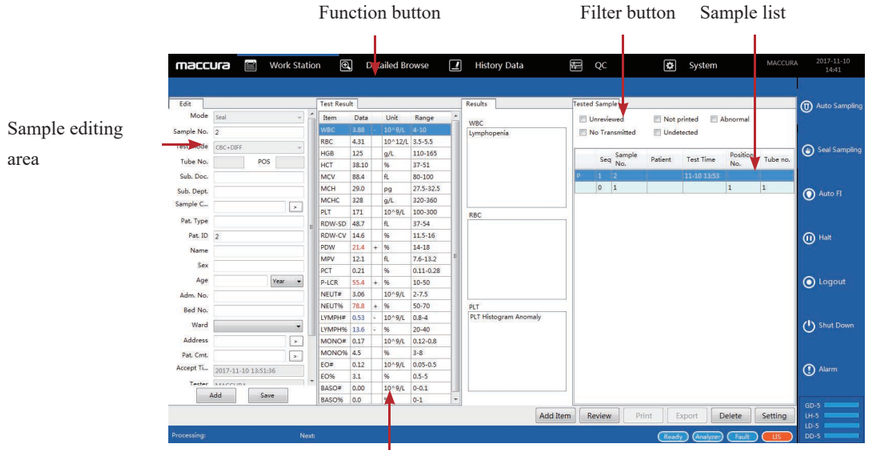


Figure 7.1-1

7.2 Function button

- “Review”
  Review the selected tested sample.
- “Print”
  Select one reviewed sample, click “print” button to preview or print.
- “Export”
  Select the results that need to upload to LIS, click "export " to upload the data to the LIS server.
- “Delete”
  Select the sample which need to be deleted, click “delete” button to delete the sample.

Important	■ When editing the sample information, it is possible to make some items invisible if they are not needed (eg. patient ID, patient address).

- “Setting”
  It can set these items invisible, such as figure 7.2-1.

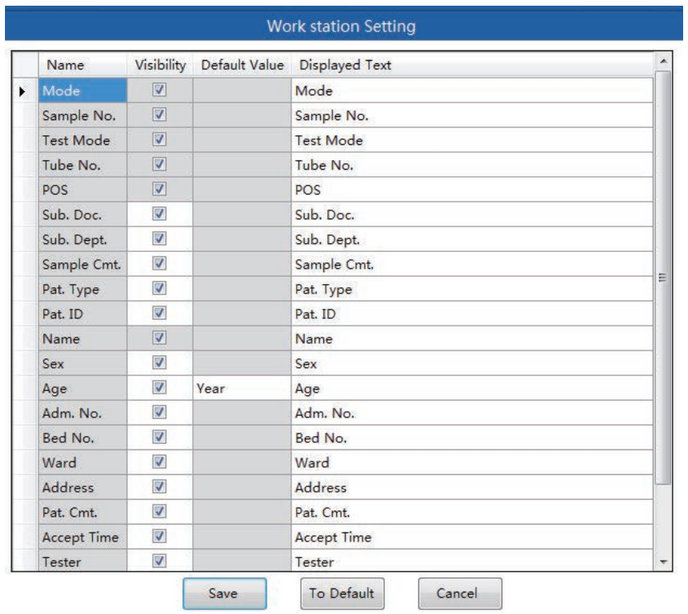


Figure 7.2-1

- Patient ID is unique and unrepeatable, system identifies patients by patient ID. When patient ID is selected as invisible, the system will automatically generate patient ID. When it is selected as visible, patient ID must be entered when input patient information.

- Only audited sample could be printed out, audited sample can cancel audit, printed sample can cancel autdit as well.

7.3 Sample editing area

1. Worksheet information input

- Click “work station” button in main menu, which is on the left side of the menu, as shown in picture 7.1-1. Click “add” button, input sample information, after that click “save” button, and then the current sample information can be saved.

- Sample number, sample mode and test mode are the necessary options, other items can be configured.
- When it needs continuously add worksheet sample, click “add” button continuously.

2. Sample modification

- Click and select one sample.
- Modify sample information in sample editing area directly.
- After finish modification, and then click “save” button.

Important	■ Only untest worksheet sample and tested but unreviewed sample can be modified.

7.4 Sample list

Work station sample list area shows sample to be test and 1000 tested regular samples in last 3 days. Quality control, background checking and imported samples are not displayed.

7.5 Analysis results area

Select one tested sample in sample list, it will display sample test results and IP flag information in analysis results area.

7.6 Filter button

After selecting tested sample in sample list, there will be a “filter” button on the top. Filter conditions consists of unreviewed, imprinted, abnormal, no transferred and test sample status.

- When it starts the procedure, three buttons cannot use, button is in‘selected’status after click the button, which means to use this filter condition. Click again to cancel this filter condition.
- These filter conditions can choose single or multiple conditions simultaneously, or do not choose them all, more specific filter based on the requirements of users.

- “Abnormal” refers to sample which alarmed by IP flag, as long as one alarm item occurs it can be regarded as abnormal sample.

Chapter 8
Results view

8.1 Overview

The analysis results will be saved to the database automatically each time. System databases can save 100,000 results including information of 28 parameters, 3 histograms, 1 scattergram and results display.

Users can choose to view batch of analysis results in the manager mode or to view a detailed analysis by the way of browser (Display histogram and scattergram).

8.2 History data

Click “history data”button in main menu, shown as picture 8.2-1.

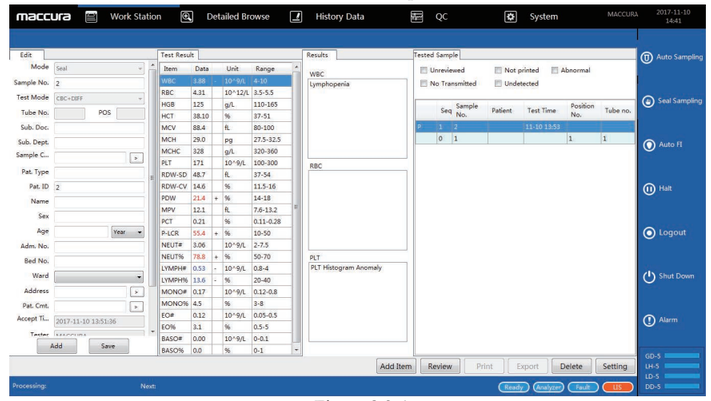


Figure 8.2-1

8.2.1 Results view

Users can view the results saved by the system in this interface. All the results will be arranged in chronological order, with the latest analysis results displayed at the top of the list. If the storage of the results exceeds the display range of the screen, a scroll bar will appear at the right of the list, and the user can drag the scroll bar to turn the page and view the results.

8.2.2 Results Select

- Single Result Selection
  User can select the analysis results that need viewing or further operation (left-click or click ↑ ↓ arrow on the menu bar) based on his/her own needs. The selected results will be highlighted as Figure 8.2.2-1 shows.

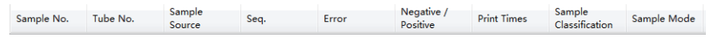


Figure 8.2.2-1

After the current result is selected, the analysis results will be displayed in the right results column as Figure 8.2.2-2 shows.

Item	Data		Unit
WBC	++++		10^9/L
RBC	10.35	@	10^12/L
HGB	0	-	g/L
MCV	----		fL
MCH	----		pg
MCHC	----		g/L
RDW-CV	----		%
RDW-SD	----		fL
HCT	++++		%
PLT	919	+	10^9/L
MPV	----		fL
PDW	----		%
PCT	----		%
BASO#	----		10^9/L
BASO%	----		%
NEUT#	----		10^9/L
NEUT%	----		%
EO#	----		10^9/L
EO%	----		%
LYMPH#	----		10^9/L
LYMPH%	----		%
MONO#	----		10^9/L
MONO%	----		%
IG#	----		10^9/L
IG%	----		%
WBC-I	++++		10^9/L
WBC-O	0.01	-	10^9/L
P-LCR	----		%

Figure 8.2.2-2

Users can also click “Sample Info.”, “CBC”, “DIFF” and “Patient Info.” in the lower left corner of the manager, select the corresponding column table for viewing, as Figure 8.2.2-3 shows.

- Sample Info. column shows the sample number, date, time of the test, the test mode and other information;
- “CBC” column displays the CBC item results of this test item and results prompt;
- “DIFF” column displays the DIFF item results of this test item and results prompt;
- “Patient Info.” column displays the name, sex and others information of patients.
- Some common columns (including sample number) often display in the left side so that users can conduct accurate search when switching columns.

Figure 8.2.2-3

- Multiple Results Selection
  Users can select the results of in bulk if needed. Press the left mouse button and drag in the management interface to select the results continuously. Press “ctrl” on the keyboard to select the needed results.

Important	■ All batch results will be highlighted, and the result column will only display the sample pointed by the arrow at the most left side.

8.2.3 Review

The sample results can not be reviewed in the historical data interface.

Important	■ Sample number starting with “QC-” is quality control data that cannot be modified. ■ Sample number starting with “QC-” is quality control data that can be deleted.

Important	■ Reviewed status displays “S” mark in review column.

8.2.4 Results Modify

Users are not allowed to modify any sample on the history data interface.

8.2.5 Results Deletion

Users can delete unwanted data according to his/her needs. The operation procedures are as follows:

1. Select the single sample or multiple samples which need to be deleted.
2. Click “delete” button at the right corner of the bottom.
3. The dialog box will be poped up as picture 8.2.5-1.

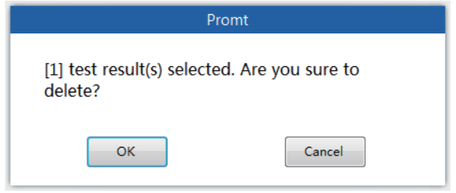


Figure 8.2.5-1

4. Click “ok” button to confirm delete, click “cancel” button to cancel the data deletion procedure.

Important	■ The number in the dialog box is the number of results which users have selected in total. ■ Reviewed sample cannot be deleted.

8.2.6 Upload the results

Select the LIS results which need to be uploaded, click “Export” and the data will be uploaded to the LIS server automatically.

Important	■ Sync feature can only be used when LIS is successfully connected. ■ After the test is completed, new sample will be uploaded to the server automatically.

8.2.7 Report Print

Users can print out reviewed results in the history data interface as follows:

1. Select the result needs printing. Click“Print”, as Figure 8.2.7-1 shows. The successfully connected printer will start printing the report list.

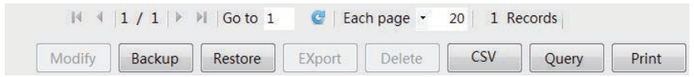


Figure 8.2.7-1

2. For a preview, click “print” button, print preview interface will pop out as Figure 8.2.7-2 shows.

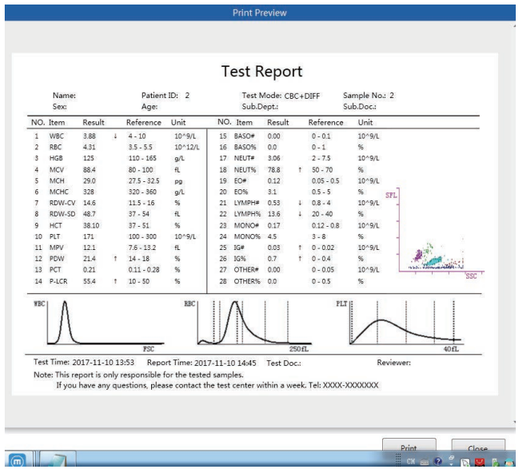


Figure 8.2.7-2

Important	■ Confirm printer installation, connection status, and whether paper supplies are sufficient before printing the report. ■ Not reviewed samples are not allowed print preview or print output.

8.2.8 Results back-up

User can back up results of selected historical data. Details for operation steps as follows:

1. Click “history data” — “back-up” button, shown as picture 8.2.8-1.

Figure 8.2.8-1

2. Choose the backup path for the selected documents in dialog box, shown as picture 8.2.8-2.

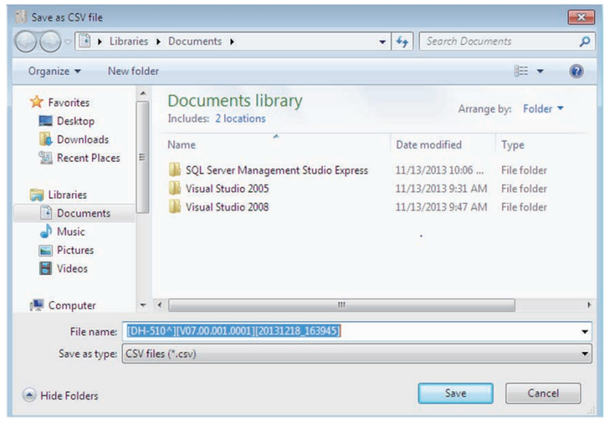


Figure 8.2.8-2

3. Click “Save” button to confirm backup, click “cancel” button to cancel current operation. Backup content consists of the sample information for the historical data, test results and graphics and patient information. User can select one data or multiple data to backup, and one data will generate only one SMP format document.

8.2.9 Results restore

User can recover the data which has already backed up, the details operation as follows:

1. Click “history data” — “restore” button, shown as picture 8.2.9-1.

Figure 8.2.9-1

2. Choose the path for the documents which need to be restored in dialog box, shown as picture 8.2.9-2, and then click “ok” button to restore.

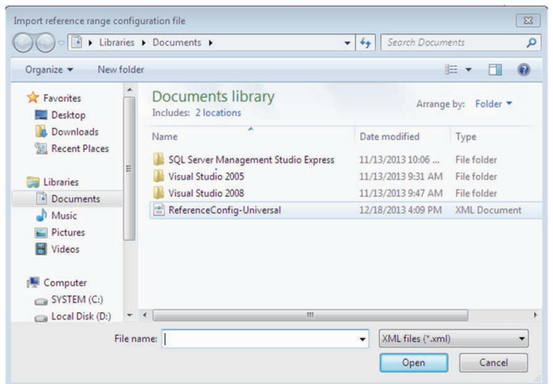


Figure 8.2.9-2

Important	■ The sample restore function can not be used while the instrument is running. ■ The restored sample is labeled "Import." Imported samples can not be reviewed and modified.

8.2.10 Results Export

Users can export single or batch results to a computer in CSV format in the manage interface, so as to use EXCEL and other statistical tools for sample analysis. Abnormal Results Prompt Choosing

Export methods are as follows:

1. Click “history data” – “CSV output” button, shown as picture 8.2.10-1.

Figure 8.2.10-1

2. The dialog box for need export pictures or not will appear, shown as picture 8.2.10-2, select output pictures or not as needed.

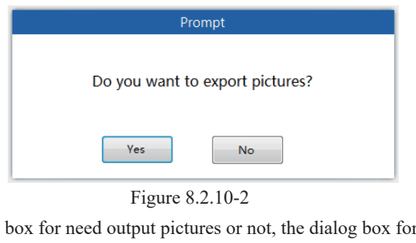


Figure 8.2.10-2

3. After click dialog box for need output pictures or not, the dialog box for output target location will appear, shown as picture 8.2.10-3.

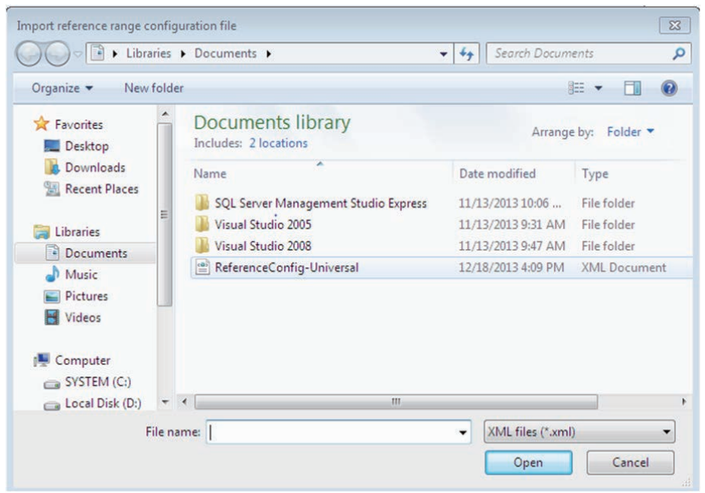


Figure 8.2.10-3

4. Click “save”, the selected results will reserve in target location with the doucument name which named by system automatically in CSV format.

5. The dialog box will appear after finishing output, shown as picture 8.2.10-4.

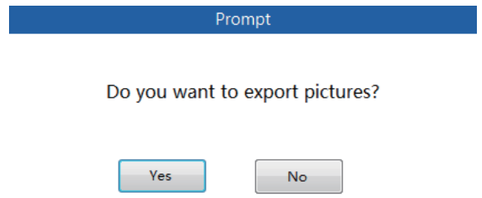


Figure 8.2.10-4

6. Click “ok” button, and log out this dialog box.

Important	■ The document name automatically generated by the system, and user can rename the document as needed by themselves. ■ Save type is CSV format only.

8.2.11 Result query

User can filter the qualified sample in history data. The details as follows:

1. Click “history data” – “query” button, shown as picture 8.2.11-1.

Figure 8.2.11-1

2. Conditional filter dialog box will appear after click “query” button, shown as picture 8.2.11-2, user can query data by selecting query condition.

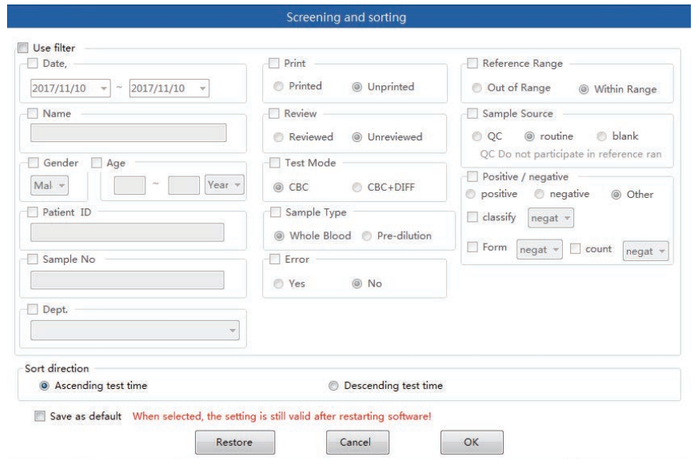


Figure 8.2.11-2

■ Query conditions

In picture 8.2.12-2 interface, select “use filter” button, and then further select the conditions which need to query simultaneously.

→ "Date" can be selected by date method to query.

→ “Name” can input patient name to query.

→ “Patient ID” can input patient ID to query.

→ “Sample number” can input sample number to query.

→ “Print” can be selected by printed, not print two methods to query.

→ “Audit” can be selected by audited, not audit two methods to query.

→ “Test mode” can be selected by CBC+DIFF mode, CBC mode, predilution CBC+DIFF mode and predilution CBC mode.

→ “Reference range” can be selected by outside reference range and inside reference range to query.

→ “Sample source” can be selected by quality control, routine sample and background checking to query.

→ “Negative/Positive” can be seleced by negative sample mode and positive sample mode.

→ “Sort direction” can select detection date by descending order and detection date by ascending order.

Important	■ Query function can be selected by choosing single condition and multiple conditions to query. ■ When selecting measure time, when the input time is greater than the end time, it prompts the user that the query is not executed; The input time cannot more than current date.

8.3 Detailed browse

Click “detailed browse” button in main menu, then the detailed browse interface will appear, shown as picture 8.3-1.

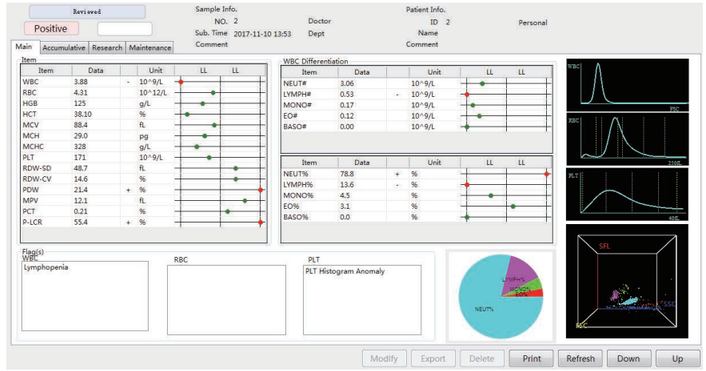


Figure 8.3-1

User can check the single sample result briefly in “detailed browse” function, which includes histogram, scattergram and negative/positive alarm information. User can select one tested sample in worksheet or history data interface, and then click “detailed browse” button in tool list to browse sample briefly. User also can click “detailed browse” button in main menu to check the latest tested sample directly.

8.3.1 Results Checking

The browser displays the currently selected sample analysis results, negative or positive alarm, review status, sample information, patient information, Flags tips and other information.

Users can view the results by clicking “Upper”/ “Lower” on the main menu, can also use the ↑ ↓ keys on the keyboard.

Click “Research” and the research interface will open as Figure 8.3.1-1 shows. In addition to the 24 report parameters displayed in the research interface, IG #, IG %, OTHER #, OTHER% 4 research parameters are also displayed.

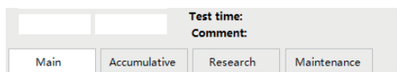


Figure 8.3.1-1

Important	■ Double click the figure for magnification.

8.3.2 Related instructions for detailed browse interface

Unreviewed samples cannot be modified or reviewed in detailed browse interface, but they can be deleted; Reviewed sample can be selected to view, preview, output and print data in detailed browsie interface, but they cannot be deleted.

Important	■ Sample number starting with “QC-” is QC data that cannot be modified. ■ Sample number starting with “QC-” is QC data that cannot be deleted.

Important	■ Reviewed results will be displayed with a green background in the status bar, and the results which have not been reviewed will be displayed with a white background in the status bar.

8.3.3 Results lock

Click “detailed browse” — “refresh” button, which could control the detailed browse interface will automatically refresh or not when the latest sample result released.

1. When the button selected as“locked”, shown as picture 8.3.3-1, the detailed browse interface will not automatically refresh when the latest sample result released.

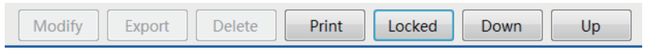


Figure 8.3.3-1

2. When the button selected as“refresh”, shown as picture 8.3.3-2, the detailed browse interface will automatically refresh when the latest sample result released.

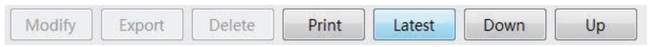


Figure 8.3.3-2

Chapter 9 Analyzer Calibration

9.1 Overview

The purpose of the analyzer calibration is to ensure accuracy of the analysis results.

Warning	■ Please pay attention in operation since aspiration pipette is fine, and the calibrator, quality control material and biological samples it carried may be biologically infectious. ■ The handling of waste calibrator, package of QC materials should comply with the local and national regulation on the discharging and handling of bio-infectious materials like reagents, waste fluid, etc.
	■ Samples, calibrator, quality control materials, and waste fluid, etc. is potentially biological infectious. The operator should comply with laboratory safe operation requirements and wear personal protective equipment (such as laboratory protective clothing, gloves, etc.).
Important	■ Only login users with administrator authority can conduct calibration. ■ Users should use the quality control material and calibrators specified by maccura, and store the calibrators, quality control materials and reagents in the strictly instructed storage environment.

The analyzer was calibrated at the factory.

After the calibration, the analyzer can ensure the accuracy of the analysis results for a long time, but under the following conditions the analyzer may need new calibration.

- First use after installation;
- Analyzer has not been used for a long time, before using;
- After the replacement of the main components;
- Observe quality control data, when deviations occur on quality control data confirms after double check.

  Analyzer provides manual calibration and automatic calibration.

  Please confirm the following conditions before calibration:
- Analyzer should meet the requirements of the background as appendix shown. If the background appears abnormal, please refer to fault handling procedure for solution. If it cannot be resolved, please contact maccura's customer service;

- Remaining reagents are sufficient to complete the calibration. If reagent shortage occurs during calibration, it should be recalibrated;
- Analyzer repeatability should meet the requirements shown in appendix. If repeatability appears abnormal, please refer to fault handling procedure for solution. If it cannot be resolved, please contact maccura's customer service.

Important	■ Repeatability test method: under the whole blood test mode, use mid-value quality control blood to count 11 times continuously, take 2nd to 11th times for analysis results, which will be exported in CSV format and then use Excel to count CV value.

9.1.1 Manual calibration Manual

calibration is as follows:

1. Prepare calibrator or fresh blood that has been tested on the reference analyzer to obtain reference value.
2. Enter the sample test interface, select CBC + DIFF mode or pre-dilution CBC+DIFF mode.
3. Test calibrator or reference values obtained fresh blood in the analyzer 11 times continuously, and calculate average of 2nd to 11th and then get the measurement average value.
4. Double click system" — "calibration" and select manual calibration.
5. Manual calibration interface will pop out as Figure 9.1.1-1. shows.

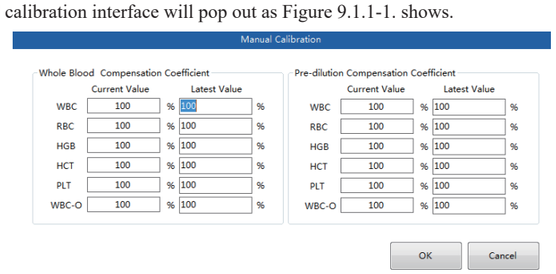


Figure 9.1.1-1

6. Calculate the new correction factor with the following formula.

$$\text{New correction factor} = \frac{\text{Current correction factor} * \text{Reference value}}{\text{Measurement mean value}}$$

7. Enter the latest correction factor in the corresponding compensation coefficient item.
8. Click "OK" to save the new modified coefficient automatically and exit the current interface.

Important	■ Only login users with administrator privileges can calibrate. ■ If fresh blood is not used, user should use quality control material and calibrators specified by maccura and store the calibrators, controls and reagents in the strictly instructed storage environment.

9.1.2 Auto Calibration

Automatic correction method is as follows:

1. Prepare calibrator or fresh blood that has been tested in the reference analyzer to obtain the reference value.
2. Click "system" — "calibration" —"automatic calibration", and then pops up the automatic calibration interface.

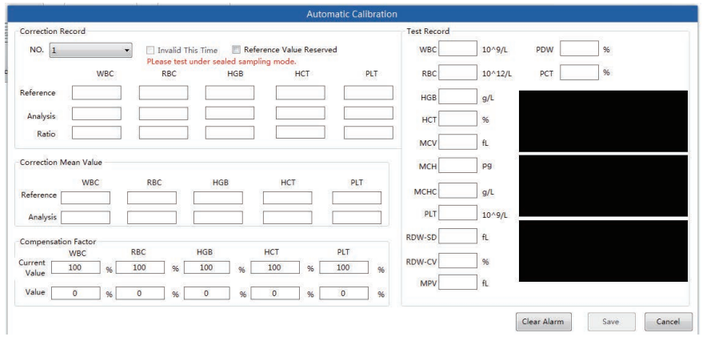


Figure 9.1.2-1

1. Test calibrator or reference values obtained fresh blood on the analyzer shoud be tested at least 5 times continuously, and each reference should be entered into the reference value input box. Select NO. values as “+1” after each test. If you are using the same blood for calibration, you can choose “Retain Reference Value” to avoid repeated input of reference value.
2. If test times are more than or equal to 5 times, the software will calculate a new correction factor automatically, click “Save” to save the calibration results.

Important	■ There will be a corresponding message if the results do not meet the specification. Please check referring to the corresponding message.

9.1.3 Correction Factor Confirmation

After system calibration, the new correction factor should be confirmed according to the following steps:
Step 1: Test the calibrator three times to make sure the analysis results are within the allowable range.
Step 2: Run the high, medium and low three concentrations of quality control material, test each concentration three times to make sure the analysis results are within the allowable range.
Step 3: Test three normal fresh blood samples whose results are already known, each sample will be tested three times to make sure the analysis results are within the allowable range.

Chapter 10 Quality control

10.1 Overview

In order to monitor the performance of analyzer in operation, performing quality control regularly is required. The laboratory should develop standardized quality control operating procedures and ensure its strict execution.
After calibration or main components replacement of the analyzer, additional quality control is required.

Important	■ Use specified quality control blood. Store the quality control material in the strictly instructed storage environment.
	■ Samples, calibrator, quality control materials, and waste fluid, etc. is potentially biological infectious. The operator should comply with laboratory safe operation requirements and wear personal protective equipment (such as laboratory protective clothing, gloves, etc.).

10.2 Quality Control Material

QC blood will be used, which could be divided into level 1, level 2 and level 3.

Important	■ Only specified quality control blood can be used. QC blood is designed to determine the state of the Analyzer.

10.3 Quality Control Methods

This analyzer use L-J QC, XBAR QC and X-M QC.
L-J QC: Single QC test data will be used daily to determine the performance of analyzer.
XBRA QC: Measure QC materials twice continuously every day, the mean value will be used to determine the performance of analyzer.
X-M QC: The mean value of the negative samples is calculated as the quality control point and is drawn on the quality control chart.

10.4 Preparation for QC

■ Turn on the device and wait for the mainframe to turn to measurement ready status.

■ New device’s QC file will have no records.
■ Create a QC file in the QC File interface.

10.5 QC File

10.5.1 QC File Input

QC file must be registered before performing quality control tests.
QC file input method is as follows:
Click “QC” button in main manu and then access to QC document interface, as Figure 10.5.1-1 shows.

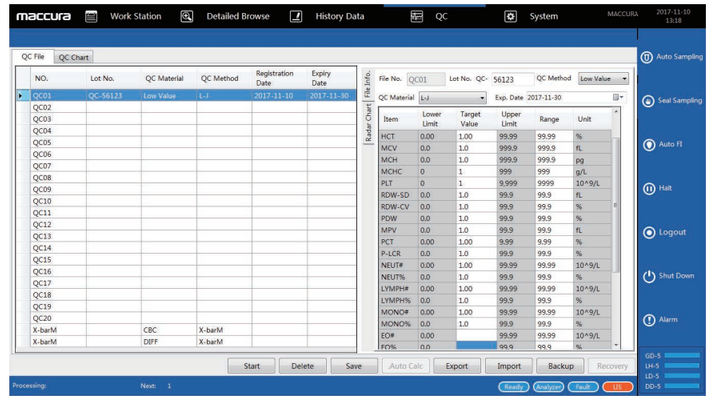


Figure 10.5.1-1

1. Select a blank QC document, and then the corresponding document information will be indicated in right side of this interface, as Figure 10.5.1-2 shows.

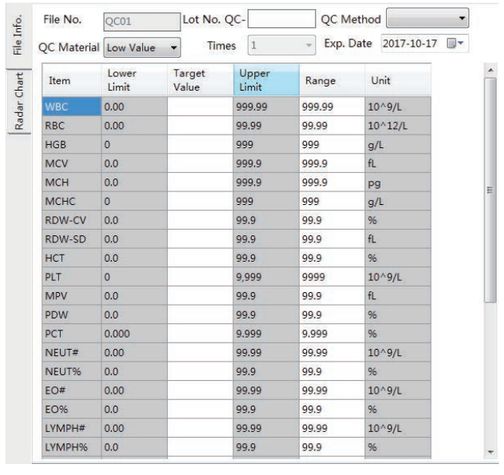


Figure 10.5.1-2

2. Enter the lot number and expiry date on the quality control packaging, and target values, limits range and other information provided in the manual as Table 10.5.1-1 shows.

Table 10.5.1-1 Input specification

Name	Meaning and Instruction
Material	QC materials selected by user, including high, medium and low levels, and clinical samples.
Item	24 report parameters provided by this analyzer, except IG#, IG%, other#, other%.
Lower Limit	= Target Value–Limit Range
Target Vale	Manually set the input; obtained from the QC materials manual
Upper Limit	= Target Value + Limit Range
Lot No.	QC materials lot number printed on the package
File No.	QC file number
Unit	The corresponding units of items set in UMS
Exp. Date	On the QC materials package, consistent with the expiry date of QC file
Manual Setting	Manually input cursor-chosen items' target values and limit vale
Save	Save the current input or modification and exit this interface

3. Click "Save" to save and exit this interface after input is completed.

Important	■ When the registered document is reentered again, it is modified.

10.5.2 QC File Modify

Users can modify the lot number information of QC file in the lot input interface. Select the QC file number whose information needs modification in the file list. Click "QC Files" on the main menu to enter the QC file modification interface.

10.5.3 Move to Previous Data

Move the cursor in the file list to the previous file and select the QC file. Click "Previous" on the main menu or press ↑ on the keyboard.

10.5.4 Move to Next Data

Move the cursor in the file list to the next file and select the QC file. Click "Next" on the main menu or press ↓ on the keyboard.

10.5.5 Delete

Select the QC file that needs deleting.

- Click to select a single file; Delete the selected file.
- When the file is selected, click "Delete" on the main menu and the confirmation dialog box pops out as Figure10.5.5-1shows.

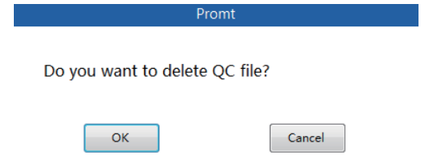


Figure 10.5.5-1

- Click "OK" to delete the selected QC file and close the dialog box.
- Click "Cancel" to cancel QC file deletion and close the dialog box.

Important	■ When the selected file does not have lot number information, the delete button is disabled.

10.6 QC Chart

Use any of the following methods to enter QC chart interface:
In the QC file interface, double click the file number that needs graphic checking, and then click "QC chart".
The data of the selected QC file will be displayed in fold line in chronological order on QC chart as Figure 10.6-1 shows.

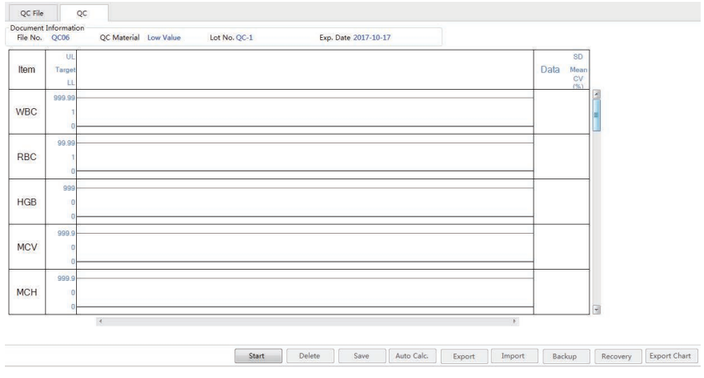


Figure 10.6-1

10.7 Perform QC analysis

QC analysis run in seal sampling mode. QC analysis consists of L-J QC, XBAR QC and X-M QC

- Control materials and waste fluid, etc. is potentially biological infectious. The operator should comply with laboratory safe operation requirements and wear personal protective equipment (such as laboratory protective clothing, gloves, etc.

Perform QC analysis in manual mode as following steps.

- When the instrument is ready, select a registered QC document and click "Start QC" on the toolbar to pop up the QC analysis interface.

10.7.1 L-J QC

L-J QC mode only run in manual sampling for once, shown as picture 10.7-

1. After finishing measurement procedure, and then click “accept” button to finish this QC.

Workflow as follows:

1. Select one L-J QC doucument which has already registered, and then click “start QC” button enter into L-J QC interface.
2. After mixing controls totally, put the tube into manual sampling box. Press “manual sample” button to start QC analysis.
3. The results will be indiciated in L-J QC interface after finishing analysis.
4. Click “accept” button to finish QC.

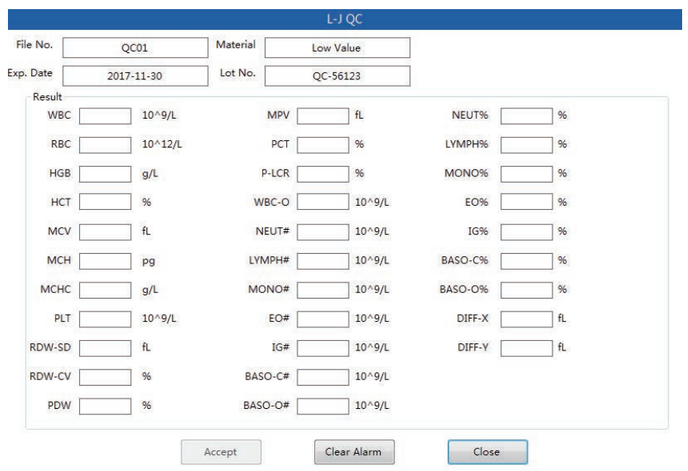


Figure 10.7-1

10.7.2 X-BAR QC

X-BAR QC run in manual sampling mode for two times, shown as picture 10.7.2-1.

After two times measurement, the instrument will get mean value, and then click “accept” button to finish X-BAR QC test.

Workflow as follows:

1. Select one X-BAR QC doucument which has already registered, and then click “start QC” button enter into X-BAR QC interface.

2. After mixing controls totally, put the tube into manual sample box. Press “manual sample” button to start QC analysis for the first time.
3. The results will be indiciated in X-BAR QC interface after finishing analysis for the first time.
4. Press “manual sample” button to start QC analysis for the second time.
5. The results will be indiciated in X-BAR QC interface after finishing analysis for the second time.
6. The system will qutomatically calculate these two analysis results, and then get the QC test results.
7. Click “accept” button to finish QC.

Figure 10.7.2-1

10.7.3 X-M QC

Use normal negative sample as QC materials, take average test results of certain number of samples as QC results and save it on the QC chart, you can choose whether or not to enable this QC method.

Workflow as follows:

1. Select“system”—“setting”—“QC”, click“start X-M QC”button, set‘X’for CBC sample numbers and “Y” for DIFF sample numbers, and then click “Ok”.

2. Fill in the target value and range information of X-M in QC.
3. Measure normal negative sample, every “X” CBC datas will generate one X-M CBC information, and every “Y” DIFF datas will generate one X-M DIFF information.
   The number of QC samples for CBC parameter can be different from DIFF parameter.
   The CBC and DIFF parameters are placed in two QC folders seperately, and QC materials can be regard as CBC and DIFF acquiescently.
   X-M QC can only calculate the sample which meet the criteria after start the analyzer this time, if restart the analyzer, the previous sample cannot be listed in the calculation range, and one sample only can be calculated once.

Important	■ X-M QC documents do not have some function, such as back-up data, restore data, output target value, input target value, export document and import document.

10.7.4 QC Analysis Results Checking

1 After QC analysis, the analysis results will be displayed in the QC acceptance interface automatically.
There are several possible displays of the QC results:

■ Results box after the item is empty “ ”, indicating that the item’s target value is not set.

■ Results box after the item display“——”, indicating error in item testing

■ Results box after the item displays red digit, indicating that the QC results exceed the set range upper and lower limits.

2 After the QC test, there are two buttons on the QC accepted interface for option.

1. Accept Accept the QC test data, save it in the corresponding QC file database and draw corresponding QC data points in the QC chart.
2. Close Cancel the QC test data, do not save it in the database of QC file.

3 View all QC data curves in QC chart interface. Monitor the performance of the device.

10.8 Abnormal results This

section is for reference only. Parameter Alarm:

■ “+” or “-” displayed on the right side of parameter names means that the obtained analysis results exceed the set reference value range, but they are still within the measurement range of the analysis.

■ “*” displayed on the right side of parameter names means that the obtained analysis results is suspicious.

■ “@” displayed on the right side of parameter names means that the obtained analysis results exceed the linear measurement range.

■ “_____” displayed on the right side of parameter names means that the obtained analysis results are invalid.

■ “++++” displayed on the right side of parameter names means that the obtained analysis results exceed the display range.

Differential or Morphological Alarm:

WBC	Criterion
WBC Abnormal Scattergram	100%<(LYMPH%+MONO%+EO%+BASO%)
Nuclear red blood cell scatter abnormal	Particle number in Ghost district ≥ 50

Neutropenia	Neut#<1*10^9/L or Neut%<0%
Neutrophilia	Neut#>11*10^9/L or Neut%>100%
Lymphopenia	Lymph#<0.8*10^9/L or Lymph%<0%
Lymphocytosis	Lymph#>4*10^9/L or Lymph%>100%
Monocytosis	Mono#>1*10^9/L or Mono%>100%
Eosinophilia	Eos#>0.7*10^9/L or Eos%>100%
Basophilia	Bas#>0.2*10^9/L or Bas%>100%
Leukocytopenia	WBC#<2.5*10^9/L
Leukocytosis	WBC#>18*10^9/L

RBC	Criterion
Erythrocyte histogram abnormal	The left and right boundaries are greater than 0.1 times the maximum value
Bimodal red blood cells	To find the wave trough in certain ranges
HGB Abormal	Rdwcv<specific value and mcv<specific value
Anisocytosis	RDW-SD>65fL or RDW-CV>20%
Microcytosis	MCV<70fL
Macrocytosis	MCV>110fL
Hypochromia	MCHC<29g/dL
Iron Deficiency?	HGB<100g/L
Erythrocytosis	RBC#>6.5*10^{12}/L

PLT	Criterion
Platelet histogram	The value in Rbcplt boundarys is greater than 0.4 times than the maximum value of plf data group, or the minimum value of plf data group is greater than 0.1 times than the maximum value of plf data group, or pdw are more than specific value
Thrombocytopenia	PLT<60*10^9/L
Thrombocytosis	PLT>600*10^9/L

Chapter 11
Maintenance

11.1 Overview

To ensure the accurate and efficient operation of the device, operators are required to conduct daily maintenance following this chapter's instructions. The analyzer provides a variety of maintenance functions, which will facilitate operators' maintenance.

Important	■ Improper maintenance might damage the analyzer. The analyzer must be maintained in accordance with the instructions. ■ If there are any problems unspecified in the instructions, please contact MACCURA's customer service for maintenance advice from professionals designated by MACCURA. ■ The analyzer must be maintained by using components provided by MACCURA. If you have any questions, please contact MACCURA's customer service.
	■ All the components surfaces of the analyzers are potentially biologically infectious, so safety precautions should be taken in the operating and maintenance process. ■ During operation, if blood or QC materials were spilled on the surface of the device, which should wipe with disinfection ethanol. During the cleaning process, safety precautions should be taken and laboratory safety requirements be followed strictly.

11.2 Maintenance

Click "System"---"Maintenance" button, shown as follow figure 11.2-1.

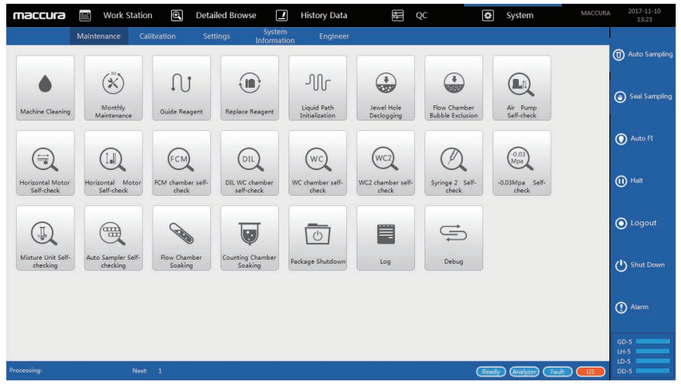


Figure 11.2-1

11.2.1 Whole Machine Cleaning

Click “Whole Machine Cleaning”, and the analyzer will automatically perform cleaning time sequence as Figure 11.2.1-1shows. The dialog box will clear automatically after cleaning.

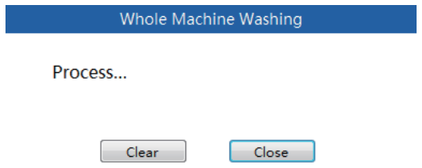


Figure 11.2.1-1

11.2.2 Jewel Hole Declogging

Click “Jewel Hole Declogging” to execute declogging time sequence. Analyzer backwashes jewl holes and burn them with a high voltage direct current on both sides to clear protein, dust and others clogged or adhered in the hole. Interface displays a progress bar of exclude plugging holes as Figure 11.2.2-1 shows.

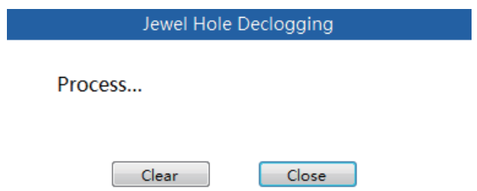


Figure 11.2.2-1

11.2.3 Flow Chamber Bubble Exclusion

Click “Flow Chamber Bubble Exclusion”, and the analyzer will execute flow chamber to remove air bubbles time sequence, and displays a progress bar as Figure 11.2.3-1 shows.

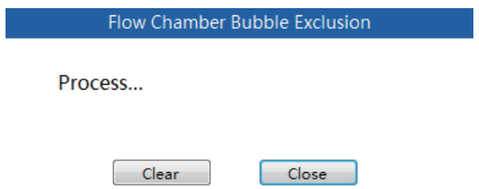


Figure 11.2.3-1

11.2.4 Liquid Path Initialization

Click “Liquid Path Initialization” and the device will automatically perform the liquid path initializing, mechanical components initializing, and the device will be restored to its original state.

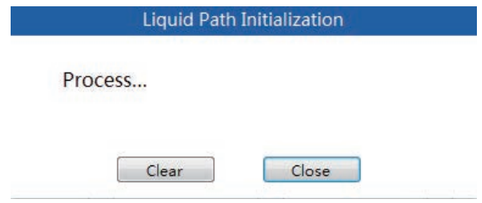


Figure 11.2.4-1

11.2.5 Sensor

Click “Sensors” to enter the sensor interface, such as figure 11.2.5-1.

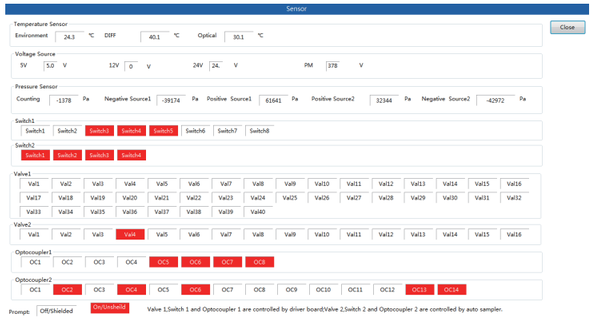


Figure 11.2.5-1

11.2.6 Blood-drawing Syringe Self-checking

Click “Blood-drawing Syringe Self-checking” and the device automatically conducts syringe self-checking as shown in Figure 11.2.6-1

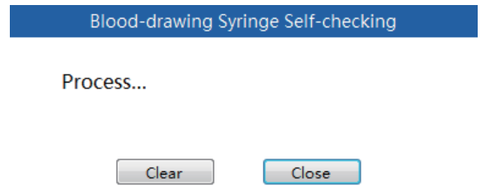


Figure 11.2.6-1

11.2.7 Monthly maintenance

Click “Monthly Maintenance” and the Monthly Maintenance confirmation interface will pop out, such as figure 11.2.7-1

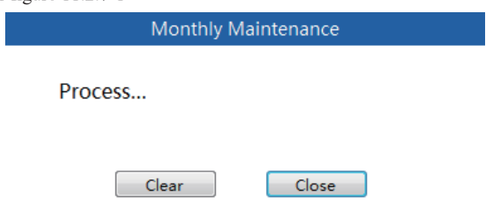


Figure 11.2.7-1

Click “Ok” to enter the Monthly Maintenance confirmation interface, such as figure 11.2.7-2

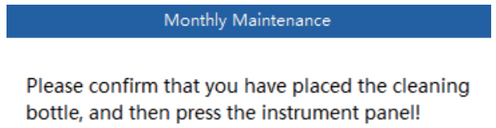


Figure 11.2.7-2

Important	■ Monthly maintenance needs to draw cleaning fluid twice. Please follow the dialog box instructions.

11.2.8 Horizontal Motor Self-checking

Click “Horizontal Motor Self-checking” the automatically executes horizontal motor self-checking. If there are any problems, system will give motor abnormal alarm, such as figure 11.2.8-1

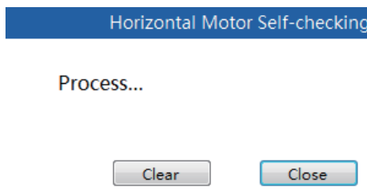


Figure 11.2.8-1

11.2.9 Vertical Motor Self-checking

Click “Vertical Motor Self-checking” the automatically executes vertical motor self-checking. If there are any problems, system will give motor abnormal alarm.

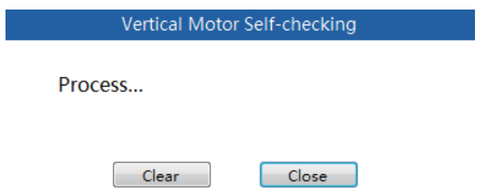


Figure 11.2.9-1

11.2.10 FCM Chamber Self-checking

Click “FCM Chamber Self-checking” and the analyzer automatically checks FCM chamber. If there are any problems, system will give FCM chamber abnormal alarm, such as 11.2.10-1

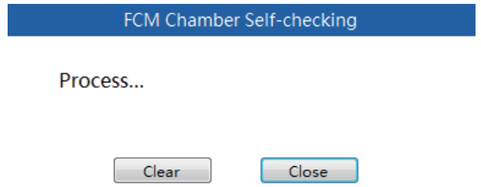


Figure 11.2.10-1

11.2.11 WC Chamber Self-checking

Click “WC Chamber Self-checking” and the analyzer automatically checks WC chamber. If there are any problems, system will give WC chamber abnormal alarm, such as figure 11.2.11-1

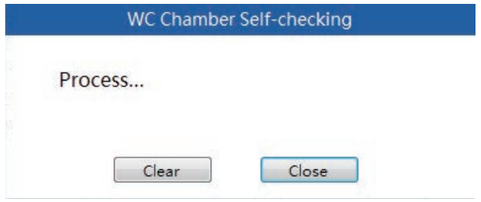


Figure 11.2.11-1

11.2.12 -0.03MPa Vacuum Self-checking

Click “-0.03MPa Self-checking” and the analyzer automatically executes -0.03MPa vacuum time sequence, such as figure 11.2.12-1

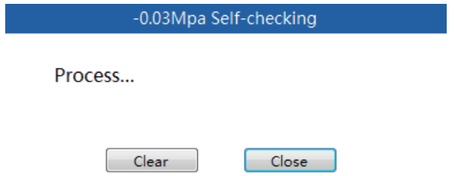


Figure 11.2.12-1

11.2.13 Reagent Replacement

Click “Reagent Replacement” to enter reagent replacement interface, such as 11.2.13-1

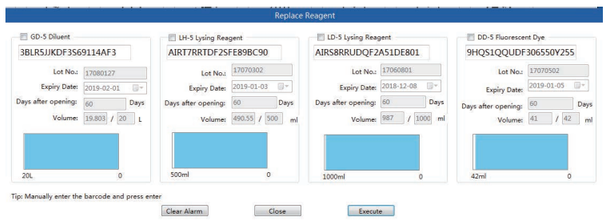


Figure 11.2.13-1

1) Check the box before the reagent that needs replacing.
2) Input the reagent scan bar in textbox.
3) Click “Execute” and the device automatically guides the reagent and replaces the reagent’s capacity, expiry date and other information in the database.

4) Click “Close” after replacement and exit reagent replacement interface.

Important	■ When replacing a reagent, the capacity of the new reagent must be put in accurately and the units must be noted.

11.2.14 Reagent Guide

Click “Reagent Guide” to enter the reagent lead interface, such as figure 11.2.14-1

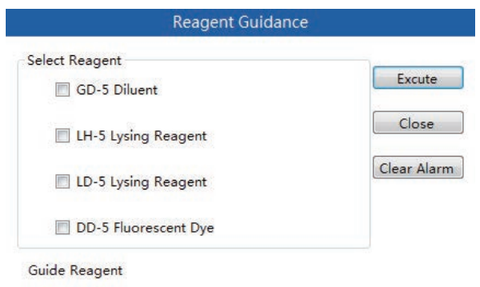


Figure 11.2.14-1

Select the box (user can select multiple reagents) before the reagent, click Execute and the device automatically guides the selected reagent(s). Click “Cancel” after the guidance and exit reagent guide interface.

11.2.15 Air Pump Self-checking

Click “Air Pump Self-checking” and the analyzer executes air pump self-checking time sequence. If the air pump is abnormal, a prompt window will pop out, such as figure 11.2.15-1.

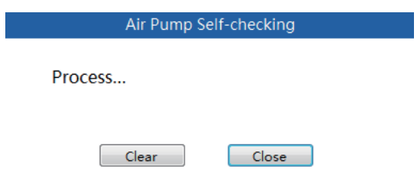


Figure 11.2.15-1

11.2.16 Counting Chamber Soaking

When there are wastes in the counting chamber, execute counting chamber soaking.

Click “Counting Chamber Soaking” and the confirmation prompt interface pops out, such as 11.2.16-1.

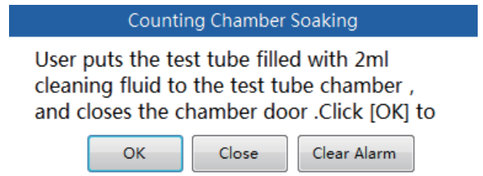


Figure 11.2.16-1

Click “ok” and the instruction dialogue window pops out.

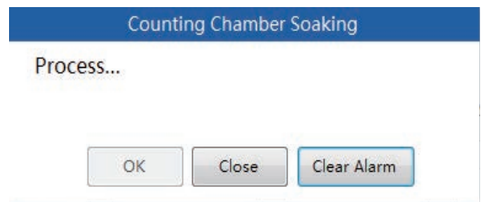


Figure 11.2.16-2

According to the instruction, place the cleaning fluid bottle under the aspiration pipette and press the key board, the device automatically draws cleaning fluid to soak.

11.2.17 Flow Chamber Soaking

When the flow chamber is dirty, execute flow chamber soaking.
Click “Flow Chamber Soaking” and the confirmation prompt window pops out， such as figure 11.2.17-1.

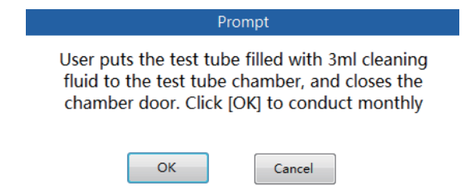


Figure 11.2.17-1

Click “OK” and the instruction window pops out, such as figure 11.2.17-2

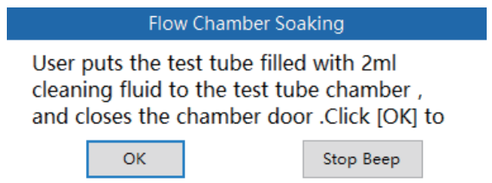


Figure 11.2.17-2

11.2.18 WC2 Chamber Self-checking

Click “WC2 Chamber Self-checking” and the analyzer automatically checks WC chamber. If there are any problems, system will give WC2 chamber abnormal alarm as shown in Figure 11.2.18-1.

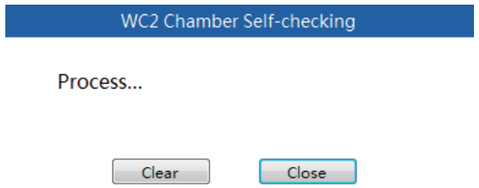


Figure 11.2.18-1

11.2.19 DIL Chamber Self-checking

Click “DIL Chamber Self-checking” button and the analyzer automatically checks DIL chamber. If there are any problems, system will give DIL chamber abnormal alarm as shown in Figure 11.19-1.

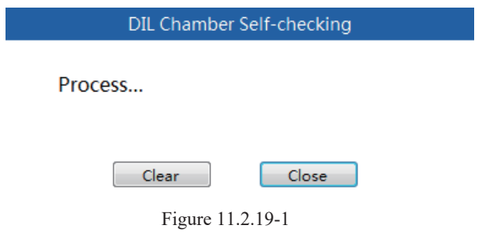


Figure 11.2.19-1

11.2.20 Mixture Unit Self-checking

Click “Mixture Unit Self-checking” and the analyzer automatically checks the mixture unit. If there are any problems, system will give mixture unit abnormal alarm as shown in Figure 112.2.20-1.

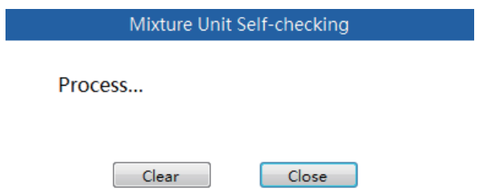


Figure 11.2.20-1

11.2.21 Automatic Sampler Self-checking

Click “Automatic Sampler Self-checking” and the analyzer automatically checks the automatic sampler. If there are any problems, system will give automatic sampler abnormal alarm as shown in Figure 11.2.21-1.

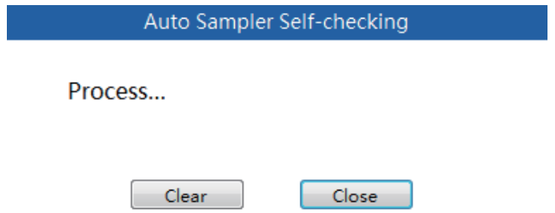


Figure 11.2.21-1

Chapter 12 Fault Handling

12.1 Overview

This chapter describes the possible faults that may occur during operation and provides appropriate solutions.

Important	■ This manual is a non-maintenance manual, and only provides solutions when the analyzer malfunctions and gives off alarm.
☣	■ Samples, calibrators, control materials, and waste fluid, etc. are potentially biological infectious. The operator should comply with laboratory safe operation requirements and wear personal protective equipment (such as laboratory protective clothing, gloves, etc.).

12.2 Fault Information and Processing

If abnormality is detected in using, the fault will be displayed in information display area of the status bar. Some of the fault information is accompanied with voice prompts.
When multiple faults appear simultaneously, user also can choose “Clear All” function, please follow as 12.2-1.

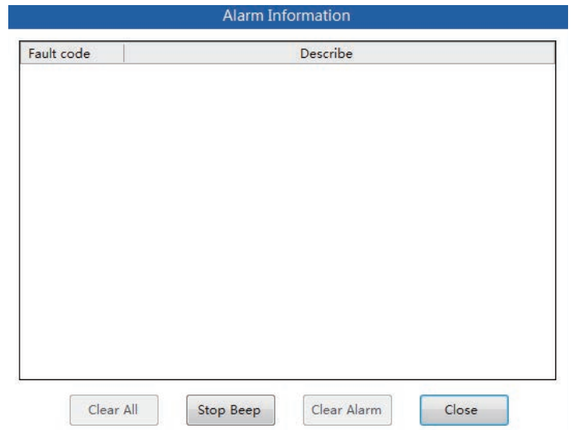


Figure 12.2-1

Fault No.	Fault Description	Executive Action	Handling Measures
1	Counting pressure is unstable	If this fault occurred during automatic sampling process, this analyzer will stop the operation	1) Double-click the fault information, detailed fault processing interface will open, click “Eliminate”. 2) If the fault cannot be eliminated, please contact MACCURA customer services or local dealers.
2	Startup DIFF chamber temperature does not reach the standard	When the fault occurred, this analyzer prompt operation	1) Reboot device. 2) If the fault cannot be eliminated, please contact MACCURA customer services or local dealers.
3	Startup optical system temperature does not reach the standard	When the fault occurred, this analyzer prompt operation	1) Reboot device. 2) If the fault cannot be eliminated, please contact MACCURA customer services or local dealers.
4	Device operation timed out	Device operation timed out When the fault occurred, this analyzer prompt operation	1) Reboot device. 2) If the fault cannot be eliminated, please contact MACCURA customer services or local dealers.
5	HGB background voltage is abnormal	If this fault occurred during automatic sampling process, this analyzer will stop the operation	1) Double-click the fault information, detailed fault processing interface will open, click “Eliminate”. 2) If the fault cannot be eliminated, please contact MACCURA customer services or local dealers.
6	Diluent insufficient	If this fault occurred during automatic sampling process, this analyzer will stop the operation	1) Double-click the fault information, detailed fault processing interface will open, click “Eliminate” to enter reagent replacement interface. Replace the diluent.
7	LH-5 lysing reagent insufficient	If this fault occurred during automatic sampling process, this analyzer will stop the operation	1) Double-click the fault information, detailed fault processing interface will open, click “Eliminate” to enter reagent replacement interface. Replace the HGB LH-5 lysing reagent.
8	LD-5 lysing reagent insufficient	If this fault occurred during automatic sampling process, this analyzer will stop the operation	1) Double-click the fault information, detailed fault processing interface will open, click “Eliminate” to enter reagent replacement interface. Replace the DIFF LD-5 lysing reagent.
9	Fluorescent dye insufficient	If this fault occurred during automatic sampling process, this analyzer will stop the operation	1) Double-click the fault information, detailed fault processing interface will open, click “Eliminate” to enter reagent replacement interface. Replace the fluorescent dye.
10	Diluent expired	If this fault occurred during automatic sampling process, this analyzer will stop the operation	1) Double-click the fault information, detailed fault processing interface will open. Click “Eliminate” to enter reagent replacement interface. Replace the diluents.

11	LH-5 lysing reagent expired	If this fault occurred during automatic sampling process, this analyzer will stop the operation	1) Double-click the fault information, detailed fault processing interface will open. Click “Eliminate” to enter reagent replacement interface. Replace the HGB LH-5 lysing reagent.
12	LD-5 lysing reagent expired	If this fault occurred during automatic sampling process, this analyzer will stop the operation	1) Double-click the fault information, detailed fault processing interface will open. Click “Eliminate” to enter reagent replacement interface. Replace the DIFF LD-5 lysing reagent.
13	Fluorescent dye expired	If this fault occurred during automatic sampling process, this analyzer will stop the operation	1) Double-click the fault information, detailed fault processing interface will open. Click “Eliminate” to enter reagent replacement interface. Replace the fluorescent dye.
14	Upper and lower machine edition mismatch	No operation	1) Change the edition of the upper and lower machine to keep consistency. Reboot upper and lower machine. 2) If the fault cannot be eliminated, please contact MACCURA customer services or local dealers.
15	Blank check does not reach the standard	Reboot the machine	1) Conduct blank check again. 2) Conduct machine wash. 3) Conduct monthly maintenance. 4) If the fault cannot be eliminated, please contact MACCURA customer services or local dealers.
16	Channel data collection error	No operation	1) Double-click the fault information, detailed fault processing interface will open, click “Eliminate”. 2) If the fault cannot be eliminated, please contact MACCURA customer services or local dealers.
17	Data storage failed	When the fault occurred, this analyzer prompt operation	1) Double-click the fault information, detailed fault processing interface will open, click “Eliminate”. 2) Reboot upper and lower machine. 3) If the fault cannot be eliminated, please contact MACCURA customer services or local dealers.
18	Thread start failed	When the fault occurred, this analyzer prompt operation	1) Reboot upper and lower machine. 2) If the fault cannot be eliminated, please contact MACCURA customer services or local dealers.
19	Serial port operation failed	When the fault occurred, this analyzer prompt operation	1) Reboot upper and lower machine. 2) If the fault cannot be eliminated, please contact MACCURA customer services or local dealers.
20	System file opening failed	When the fault occurred, this analyzer prompt operation	1) Reboot upper and lower machine. 2) If the fault cannot be eliminated, please contact MACCURA customer services or local dealers.
21	Version reading failed	When the fault occurred, this analyzer prompt operation	1) Reboot upper and lower machine. 2) If the fault cannot be eliminated, please contact MACCURA customer services or local dealers.

22	Memory error	When the fault occurred, this analyzer prompt operation	1) Reboot upper and lower machine. 2) If the fault cannot be eliminated, please contact MACCURA customer services or local dealers.
23	Time sequence download failed	When the fault occurred, this analyzer prompt operation	1) Reboot upper and lower machine. 2) If the fault cannot be eliminated, please contact MACCURA customer services or local dealers.
24	Unknown command	Stop	1) Reboot upper and lower machine. 2) If the fault cannot be eliminated, please contact MACCURA customer services or local dealers.
25	Communication with the device off! Reboot the device	Stop	1) Reboot upper and lower machine. 2) If the fault cannot be eliminated, please contact MACCURA customer services or local dealers.
26	Time sequence timeout, please clear the fault in fault elimination interface	When the fault occurred, this analyzer prompt operation	1) Reboot upper and lower machine. 2) If the fault cannot be eliminated, please contact MACCURA customer services or local dealers.
27	Serial port communication error	Stop	1) Reboot upper and lower machine. 2) If the fault cannot be eliminated, please contact MACCURA customer services or local dealers.
28	TCP communication error	Stop	1) Reboot upper and lower machine. 2) If the fault cannot be eliminated, please contact MACCURA customer services or local dealers.
29	Function time sequence not found	Stop	1) Reboot upper and lower machine. 2) If the fault cannot be eliminated, please contact MACCURA customer services or local dealers.
30	Sub time sequence not found	Stop	1) Reboot upper and lower machine. 2) If the fault cannot be eliminated, please contact MACCURA customer services or local dealers.
31	Function instruction execution time-out	Stop	1) If the fault cannot be eliminated, please contact MACCURA customer services or local dealers.
32	Pressure is too high	Stop	1) Double-click the fault information, detailed fault processing interface will open, click “Eliminate”. 2) Perform vacuum pump self-checking procedures. 3) If the fault cannot be eliminated, please contact MACCURA customer services or local dealers.
33	Pressure is too low	Stop	1) Double-click the fault information, detailed fault processing interface will open, click “Eliminate”. 2) Perform vacuum pump self-checking procedures. 3) If the fault cannot be eliminated, please contact MACCURA customer services or local dealers.

34	High vacuum	Stop	1) Double-click the fault information, detailed fault processing interface will open, click “Eliminate”. 2) Perform vacuum pump self-checking procedures. 3) If the fault cannot be eliminated, please contact MACCURA customer services or local dealers.
35	Low vacuum	Stop	1) Double-click the fault information, detailed fault processing interface will open, click “Eliminate”. 2) Perform vacuum pump self-checking procedures. 3) If the fault cannot be eliminated, please contact MACCURA customer services or local dealers.
36	DIFF chamber temperature is too high	Report them during start the machine	1) Please contact MACCURA customer services or local dealers.
37	DIFF chamber temperature is too low	Report them during start the machine	1) Please contact MACCURA customer services or local dealers.
38	DIFF chamber temperature sensor is broken	If the fault occurred during automatic measuring process, the analyzer will stop after finishing the measuring sample	1) Please contact MACCURA customer services or local dealers.
39	Optical system temperature is too high	Report them during start the machine	1) Please contact MACCURA customer services or local dealers.
40	Optical system temperature is too low	Report them during start the machine	1) Please contact MACCURA customer services or local dealers.
41	Optical system temperature sensor is broken	Delayed shutdown	1) Please contact MACCURA customer services or local dealers.
42	Environment temperature is too high	Report them during start the machine	1) Observe whether the indoor temperature is within the allowable range of the device. 2) If not, please turn on the A/C to make indoor temperature meet the requirements.
43	Environment temperature is too low	Report them during start the machine	1) Observe whether the indoor temperature is within the allowable range of the device. 2) If not, please turn on the A/C or heating to make indoor temperature meet the requirements.
44	Environment temperature sensor is broken	Delayed shutdown	1) Please contact MACCURA customer services or local dealers.
45	Horizontal motor is abnormal	If the fault occurred during automatic measuring process, the analyzer will stop after finishing the measuring sample	1) Double-click the fault information, detailed fault processing interface will open, click “Eliminate”. 2) If the fault cannot be eliminated, please contact MACCURA customer services or local dealers.

46	Vertical motor is abnormal	If the fault occurred during automatic measuring process, the analyzer will stop after finishing the measuring sample	1) Double-click the fault information, detailed fault processing interface will open, click “Eliminate”. 2) If the fault cannot be eliminated, please contact MACCURA customer services or local dealers.
47	Syringe 1 is abnormal	If the fault occurred during automatic measuring process, the analyzer will stop after finishing the measuring sample	1) Double-click the fault information, detailed fault processing interface will open, click “Eliminate”. 2) If the fault cannot be eliminated, please contact MACCURA customer services or local dealers.
48	Syringe 2 is abnormal	If the fault occurred during automatic measuring process, the analyzer will stop after finishing the measuring sample	1) Double-click the fault information, detailed fault processing interface will open, click “Eliminate”. 2) If the fault cannot be eliminated, please contact MACCURA customer services or local dealers.
49	Communication abnormal	If the fault occurred during automatic measuring process, the analyzer will stop after finishing the measuring sample	1) Reboot upper and lower machine. 2) If the fault cannot be eliminated, please contact MACCURA customer services or local dealers.
50	Waste tank is not empty	If the fault occurred during automatic measuring process, the analyzer will stop after finishing the measuring sample	1) Double-click the fault information, detailed fault processing interface will open, click “Eliminate”. 2) If the fault cannot be eliminated, please contact MACCURA customer services or local dealers.
51	Waste bucket full	If the fault occurred during automatic sampling process, the analyzer will stop	1) Empty the waste bucket. 2) Double-click the fault information, detailed fault processing interface will open, click “Eliminate”. 3) If the fault cannot be eliminated, please contact MACCURA customer services or local dealers.
52	FCM chamber is not full	If the fault occurred during automatic sampling process, the analyzer will stop	1) Check whether there are enough diluents. 2) Double-click the fault information, detailed fault processing interface will open, click “Eliminate”. 3) If the fault cannot be eliminated, please contact MACCURA customer services or local dealers.
53	Left door open	Prompt in standby, stop when runnin	1) Close the left door. 2) Double-click the fault information, detailed fault processing interface will open, click “Eliminate”. 3) If the fault cannot be eliminated, please contact MACCURA customer services or local dealers.
54	Right door open	Prompt in standby, stop when running	1) Close the right door. 2) Double-click the fault information, detailed fault processing interface will open, click “Eliminate”. 3) If the fault cannot be eliminated, please contact MACCURA customer services or local dealers.

55	Optical shielding box open	Prompt in standby, stop when running	1) Close the optical shielding box. 2) Double-click the fault information, detailed fault processing interface will open, click “Eliminate”. 3) If the fault cannot be eliminated, please contact MACCURA customer services or local dealers.
56	Laser current is abnormal	If the fault occurred during automatic sampling process, the analyzer will stop	1) Please contact MACCURA customer services or local dealers.
57	+12V voltage is abnormal	If the fault occurred during automatic sampling process, the analyzer will stop	1) Please contact MACCURA customer services or local dealers.
58	-12V voltage is abnormal	If the fault occurred during automatic sampling process, the analyzer will stop	1) Please contact MACCURA customer services or local dealers.
59	+5V voltage is abnormal	If the fault occurred during automatic sampling process, the analyzer will stop	1) Please contact MACCURA customer services or local dealers.
60	RBC jewel hole clogging	If the fault occurred during automatic sampling process, the analyzer will stop	1) Double-click the fault information, detailed fault processing interface will open, click “Eliminate”. 2) Execute counting chamber soaking. 3) If the fault cannot be eliminated, please contact MACCURA customer services or local dealers.
61	WBC jewel hole clogging	If the fault occurred during automatic sampling process, the analyzer will stop	1) Double-click the fault information, detailed fault processing interface will open, click “Eliminate”. 2) Execute counting chamber soaking. 3) If the fault cannot be eliminated, please contact MACCURA customer services or local dealers.
62	HGB voltage is abnormal	If the fault occurred during automatic sampling process, the analyzer will stop	1) Double-click the fault information, detailed fault processing interface will open, click “Eliminate”. 2) Execute counting chamber soaking. 3) If the fault cannot be eliminated, please contact MACCURA customer services or local dealers.
63	Mechanical hand ascending and descending abnormal	If the fault occurred during automatic measuring process, the analyzer will stop after finishing the measuring sample	1) Double-click the fault information, detailed fault processing interface will open, click “Eliminate”. 2) Execute counting chamber soaking. 3) If the fault cannot be eliminated, please contact MACCURA customer services or local dealers.

64	Mechanical hand clamping abnormal	If the fault occurred during automatic measuring process, the analyzer will stop after finishing the measuring sample	1) Double-click the fault information, detailed fault processing interface will open, click “Eliminate”. 2) Execute counting chamber soaking. 3) If the fault cannot be eliminated, please contact MACCURA customer services or local dealers.
65	Mechanical hand mixing abnormal	If the fault occurred during automatic measuring process, the analyzer will stop after finishing the measuring sample	1) Double-click the fault information, detailed fault processing interface will open, click “Eliminate”. 2) Execute counting chamber soaking. 3) If the fault cannot be eliminated, please contact MACCURA customer services or local dealers.
66	Test tube rack loading abnormal	If the fault occurred during automatic measuring process, the analyzer will stop after finishing the measuring sample	1) Double-click the fault information, detailed fault processing interface will open, click “Eliminate”. 2) Execute counting chamber soaking. 3) If the fault cannot be eliminated, please contact MACCURA customer services or local dealers.
67	Test tube rack feed abnormal	If the fault occurred during automatic measuring process, the analyzer will stop after finishing the measuring sample	1) Double-click the fault information, detailed fault processing interface will open, click “Eliminate”. 2) Execute counting chamber soaking. 3) If the fault cannot be eliminated, please contact MACCURA customer services or local dealers.
68	Test tube offloading abnormal	If the fault occurred during automatic measuring process, the analyzer will stop after finishing the measuring sample	1) Double-click the fault information, detailed fault processing interface will open, click “Eliminate”. 2) Execute counting chamber soaking. 3) If the fault cannot be eliminated, please contact MACCURA customer services or local dealers.
69	Sample cabin abnormal	If the fault occurred during automatic measuring process, the analyzer will stop	1) Double-click the fault information, detailed fault processing interface will open, click “Eliminate”. 2) Execute counting chamber soaking. 3) If the fault cannot be eliminated, please contact MACCURA customer services or local dealers.
70	Offloading platform is full	If the fault occurred during automatic measuring process, the analyzer will stop	1) Double-click the fault information, detailed fault processing interface will open, click “Eliminate”. 2) Execute counting chamber soaking. 3) If the fault cannot be eliminated, please contact MACCURA customer services or local dealers.
71	Test tube rack is improperly moved	If the fault occurred during automatic measuring process, the analyzer will stop	1) Double-click the fault information, detailed fault processing interface will open, click “Eliminate”. 2) Execute counting chamber soaking. 3) If the fault cannot be eliminated, please contact MACCURA customer services or local dealers.
72	Test tube rack move abnormal	If the fault occurred during automatic measuring process, the analyzer will stop	1) Double-click the fault information, detailed fault processing interface will open, click “Eliminate”. 2) Execute counting chamber soaking. 3) If the fault cannot be eliminated, please contact MACCURA customer services or local dealers.
73	Automatic sampling enabling abnormal	When the fault occurred, this analyzer prompt operation	1) Double-click the fault information, detailed fault processing interface will open, click “Eliminate”. 2) Execute counting chamber soaking. 3) If the fault cannot be eliminated, please contact MACCURA customer services or local dealers.
74	Automatic sampling recovering abnormal	When the fault occurred, this analyzer prompt operation	1) Double-click the fault information, detailed fault processing interface will open, click “Eliminate”. 2) Execute counting chamber soaking. 3) If the fault cannot be eliminated, please contact MACCURA customer services or local dealers.
75	Test tube rack does not exist	When the fault occurred, this analyzer prompt operation	1) Double-click the fault information, detailed fault processing interface will open, click “Eliminate”. 2) Execute counting chamber soaking. 3) If the fault cannot be eliminated, please contact MACCURA customer services or local dealers.

Appendix
Specification

1. Products Classification

F 580/F 580L/F 580S classification criteria are described as following:

- Classified by China Medical Device Management:
  Belongs to blood analysis systems of the clinical testing instruments (6840), management class is class II .
- Classified by shock protection:
  Belongs to class I.
- Classified by protection degree against harmful liquid:
  The related pollution level of this instrument is level 2, and the material group is group III.

2. Vacuum vessel type

	Diameter (Tube body)	Length	Remarks
Standard	12mm	75mm	/
Allowed diameter	12-15mm	/	/

Please use the suitable adapter for different diameter vacuum vessel.
Open sampling allows the use of microvessels with length less than the upper table.

3. Parameter Description

Abbreviation	Name	Default Units
WBC	White Blood Cell Count	10^9/L
RBC	Red Blood Cell Count	10^{12}/L
HGB	Hemoglobin	g/L
MCV	Mean Corpuscular Volume	fL
MCH	Mean Corpuscular Hemoglobin	pg
MCHC	Mean Corpuscular Hemoglobin Concentration	g/L
RDW-CV	RBC Distribution Width-Coefficient of Variation	%
RDW-SD	RBC Distribution Width-Standard Deviation	fL
HCT	Hematocrit	%
PLT	Platelet Count	10^9/L
P-LCR	Large platelet ratio	%
MPV	Mean Platelet Volume	fL
PDW	Platelet Distribution Width	%
PCT	Platelet Hematocrit	%
BASO#	Basophilic Granulocyte	10^9/L
BASO%	Basophilic Granulocyte Percentage	%
NEUT#	Neutrophile Granulocyte	10^9/L
NEUT%	Neutrophile Granulocyte Percentage	%
EO#	Eosinophilic Granulocyte	10^9/L
EO%	Eosinophilic Granulocyte Percentage	%
LYMPH#	Lymphocyte	10^9/L

LYMPH%	Lymphocyte Percentage	%
MONO#	Monocyte	10^9/L
MONO%	Monocyte Percentage	%
IG #	Immature Granulocyte (research)	10^9/L
IG%	Immature Granulocyte Percentage (research)	%
OTHER#	Other Cell (research)	10^9/L
OTHER%	Other Cell Percentage (research)	%
WBC Histogram	White Blood Cell Histogram	None
RBC Histogram	Red Blood Cell Histogram	None
PLT Histogram	Platelet Histogram	None
DIFF Scattergram	Scattergram	None

4. Sample Characteristics

- Sample required for each analysis (CBC+Diff) Open sampling-whole blood 20μL
  Open sampling-pre-dilution 91.5μL
- Dilution Ratio

	WBC/HGB	RBC/PLT	WBC Differentiation
Whole blood	1:349	1:16720	1:140
Capillary blood	1:627	1:32425	1:254

- Measurement Time
  Automatic sampling: no less than 75 samples/hours Manual sampling: ≤ 60 75 seconds / test

5. Performance Indicators

- Background Range

Parameters	Blank Counting
WBC	≤ 0.5×10^9/L
RBC	≤ 0.05×10^{12}/L
HGB	≤ 2g/L
PLT	≤ 10×10^9/L

- Linearity Range

Parameters	Linear Measurement Range	Linear Tolerance	r
WBC	1.0×10^9/L ~ 10.0×10^9/L	Less than±0.5×10^9/L	≥ 0.990
	10.1×10^9/L ~ 99.9×10^9/L	Less than±5.0%	
RBC	0.30×10^{12}/L ~ 1.00×10^{12}/L	Less than±0.05×10^{12}/L	≥ 0.990
	1.01×10^{12}/L ~ 7.00×10^{12}/L	Less than±5.0%	
HGB	20g/L ~ 70g/L	Less than±2g/L	≥ 0.990
	71g/L ~ 240g/L	Less than±3%	
PLT	20×10^9/L ~ 100×10^9/L	Less than±10×10^9/L	≥ 0.990
	101×10^9/L ~ 999×10^9/L	Less than±10.0%	

- Precision

Parameters	Precision	Conditions
WBC	≤ 4.0%	WBC (4.0~10.0 $\times10^9$ / L)
RBC	≤ 2.0%	RBC (3.50~5.50$\times10^{12}$ / L)
HGB	≤ 2.0%	HGB (110~160g/L)
HCT/MCV	≤ 3.0% ≤ 3.0%	MCV (35% ~ 50%, 80fL ~ 100fL)
PLT	≤ 8.0%	PLT (100 $\times10^9$/L ~300 $\times10^9$/L)

- Accuracy

Parameter	Allowed bias range
WBC	Less than±5.0%
RBC	Less than±2.0%
HGB	Less than±2.0%
PLT	Less than±8.0%
HCT/MCV	Less than±2.0%

- Carryover Rate

Parameter	Carryover Rate
WBC	≤ 3.5%
RBC	≤ 2.0%
HGB	≤ 2.0%
PLT	≤ 5.0%

Boundary Dimension and Weight

	Analyzer Mainframe
Width	550mm

Deep	700mm
Height	600mm
Weight	55kg

7. Accessories list

Item No.	Quantity	Accessories Name
1	1	Waste Fluid Bucket Soft Bag
2	1	Operator’s Manual
3	1	Ground Wire
4	1	Software Installation Thumb Drive
5	1	External Waste Fluid Bucket Tube
6	1	External Diluent Tube
7	1	External LD-5 Lysing Reagent Tube
8	1	External LH-5 Lysing Reagent Tube
9	1	Certificate
10	1	British standard power cable
11	1	American standard power cable
12	1	European standard power cable
13	1	Adapter-1
14	1	Adapter-2
15	1	Handheld Barcode Scaner (Optional)
16	6	Sample Rack（F 580）
17	5	Sample Rack（F 580L）
18	4	Sample Rack（F 580S）