

Roche *cobas* b221

血液氣體多功能分析儀產品介紹及說明



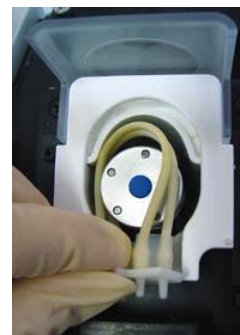
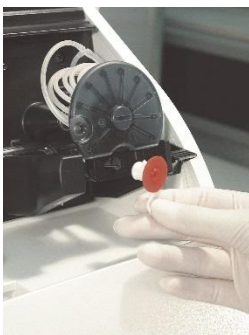
2016.11.25

威力德生醫股份有限公司

吳至德

Roche *cobas* b221

先進的多參數急診血液氣體分析儀



Roche *cobas b221*

儀器性能

Roche *cobas* 221 – 儀器性能

組合模式:

- Roche OMNI *cobas* 221 1 (BG/tHb/SO₂)
- Roche OMNI *cobas* 221 2 (BG/COOX)
- Roche OMNI *cobas* 221 3 (BG/ISE/tHb/SO₂)
- Roche OMNI *cobas* 221 4 (BG/ISE/COOX)
- Roche OMNI *cobas* 221 5 (BG/ISE/MSS***/tHb/SO₂)
- Roche OMNI *cobas* 221 6 (BG/ISE/MSS*/COOX)

MSS: * Glu, Lac, Urea/BUN ** Urea/BUN, Crea *** Glu, Lac

Roche cobas 221 – 儀器性能



- 分析速度

模組組合

分析速度[樣本/小時]

注射器

毛细管

BG - tHb/SO₂ or COOX

33

29

BG - ISE - tHb/SO₂ or COOX

32

28

BG - ISE - MSS - tHb/SO₂ or COOX

30

27

- 檢體測量時間

模組組合

測量時間

全部時間 顯示時間 display

BG - tHb/SO₂ / COOX

110s

66s/75s

BG - ISE - tHb/SO₂ / COOX

115 s/110s

66s/75s

BG - ISE - Glu/Lac - tHb/SO₂ or COOX

115s/120s

88 s/88s

BG - ISE - Glu/Lac/Urea - COOX

120s

120s

Roche *cobas* 221 – 儀器性能



- 檢體量

模組組合

- BG - tHb/ SO_2 or COOX
BG - ISE - tHb/ SO_2 or COOX
BG - ISE - MSS - tHb/ SO_2 or COOX

檢體量 [μL]

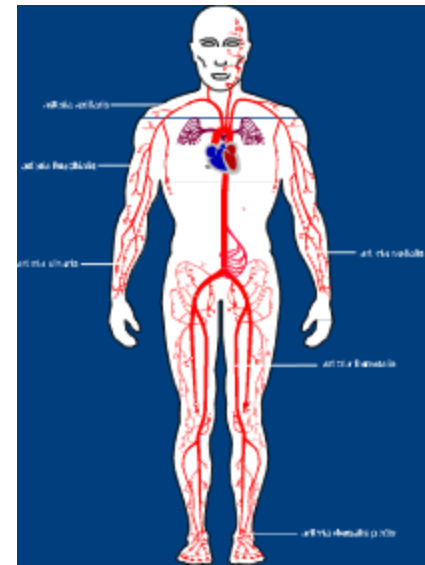
100

140

200

- 檢體種類

全血, 血清, 血漿, 透析液, 品管液 等



Roche *cobas* 221 – 儀器性能



- 儲存條件
 - 儀器 -20 °C to +50 °C
- 電極:
 - BG, ISE +2 °C to +30 °C
 - MSS (Glu, Lac, Urea/BUN) +2 °C to +8 °C
- 試劑:
 - S1 試劑 +2 °C to +30 °C (≤ 24 months)
 - S2 試劑包 +2 °C to +30 °C (≤ 18 months)
 - S3 試劑包 A (Glu, Lac, Urea/Bun) +2 °C to +25 °C (≤ 18 months)

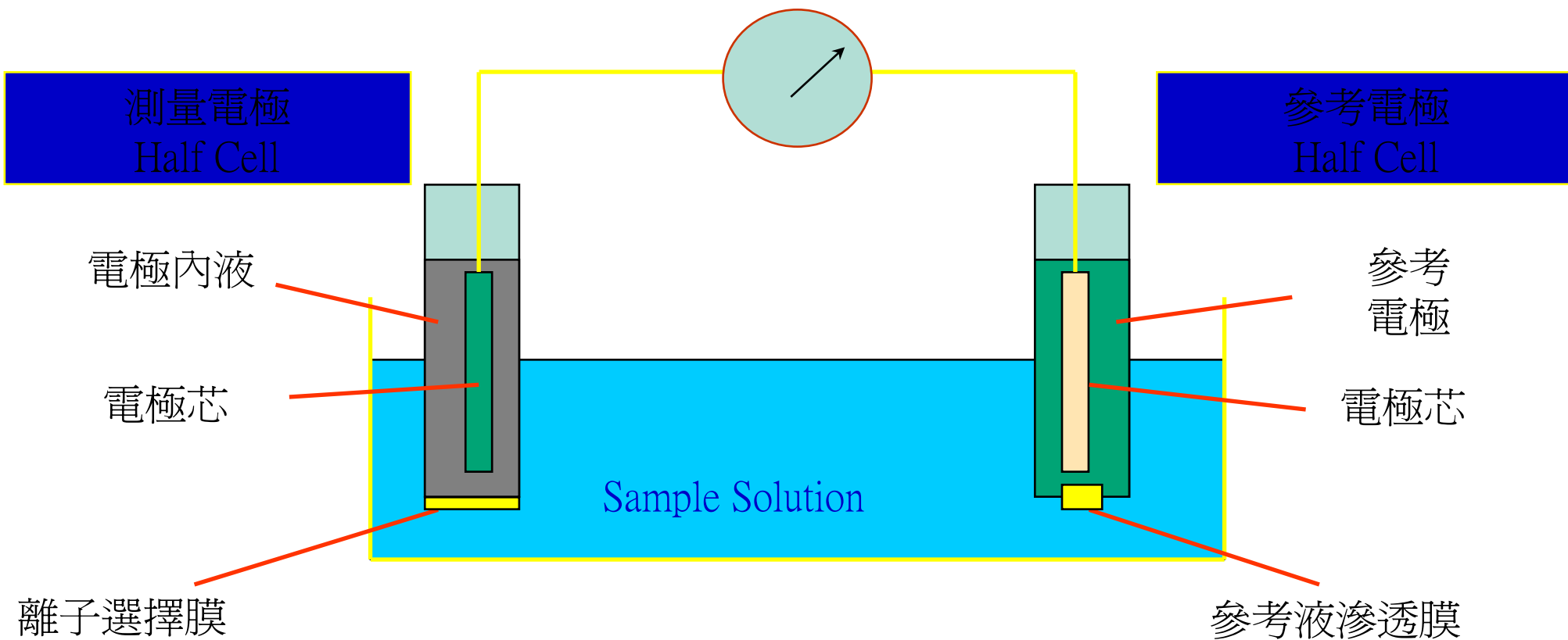
Roche *cobas b221*

測量原理

Roche cobas 221 – 測量原理

離子選擇電極

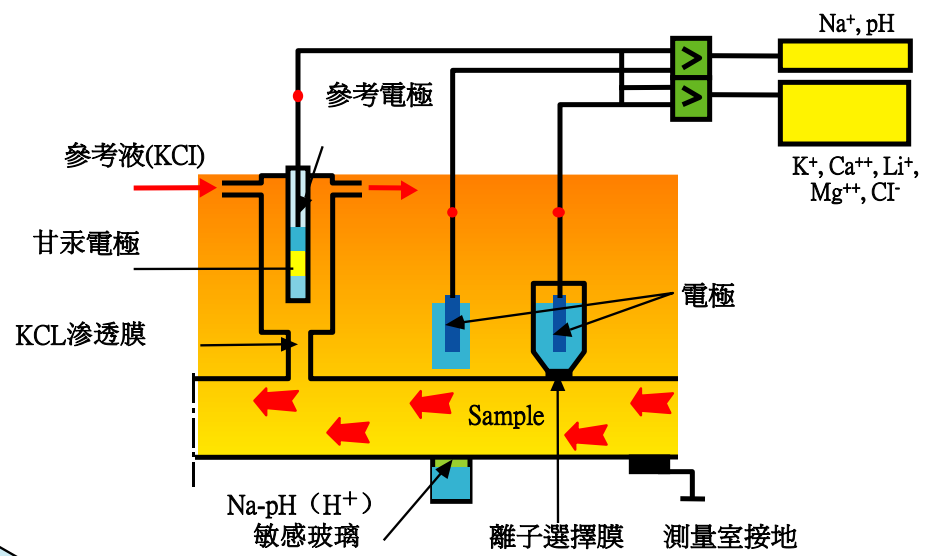
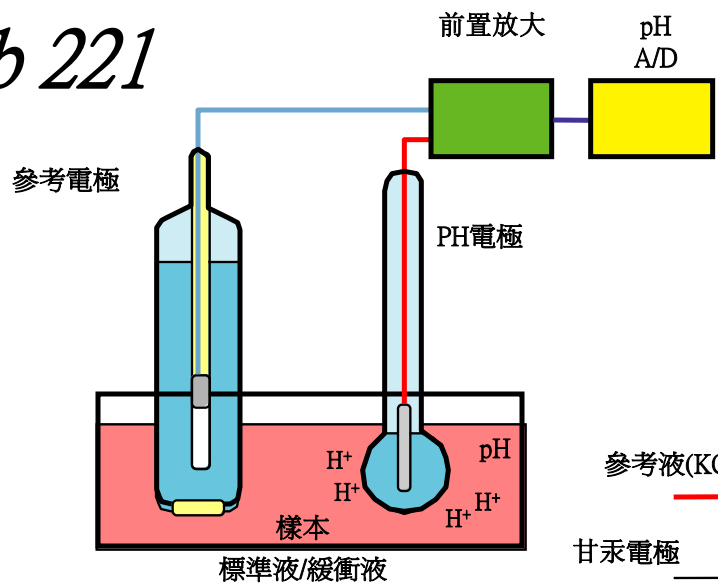
測量電流計 EMF



Roche cobas 221



Diagnostics



電極

血氣電極

pH	電壓測定法 (H^+ 離子選擇玻璃)
pCO ₂	電壓測定法 (CO ₂ 樹脂選擇膜)
pO ₂	電流測定法 (極化電極法, O ₂ 選擇膜)

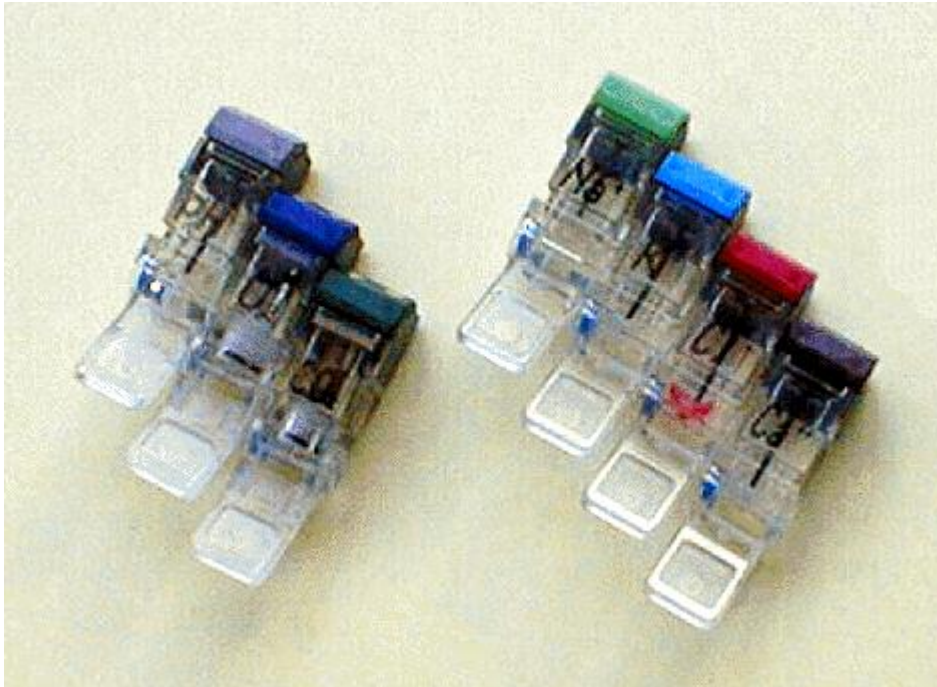
離子電極

Na ⁺	電壓測定法 (Na ⁺ 選擇玻璃)
K ⁺	電壓測定法 (生物離子選擇膜)
Cl ⁻	電壓測定法 (PVC 離子選擇膜)
Ca ⁺⁺	電壓測定法 (PVC 離子選擇膜)

參考電極: Ag/AgCl 電極

Roche *cobas* 221 – 測量原理

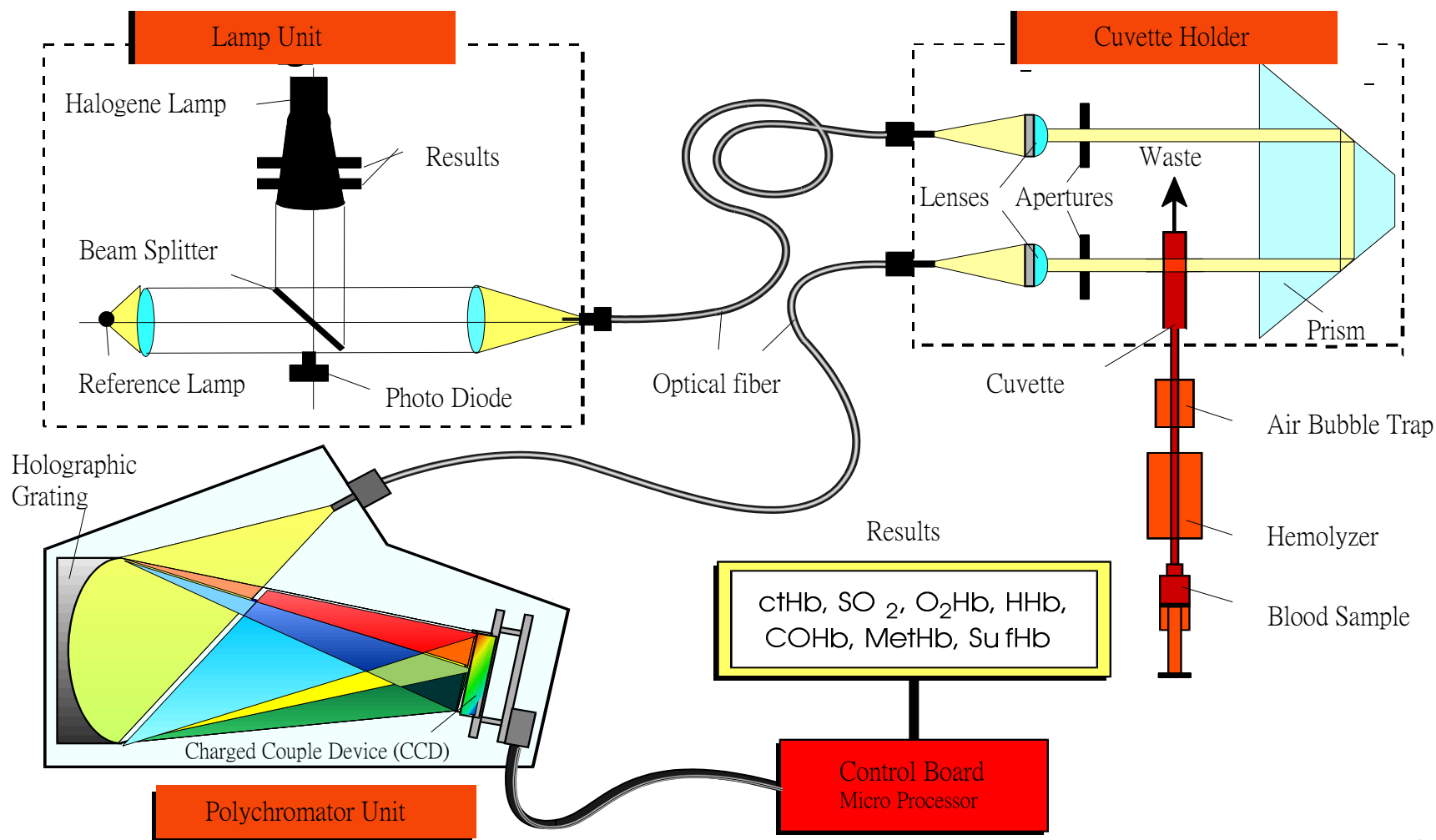
BG ISE 電極



Roche *cobas* 221

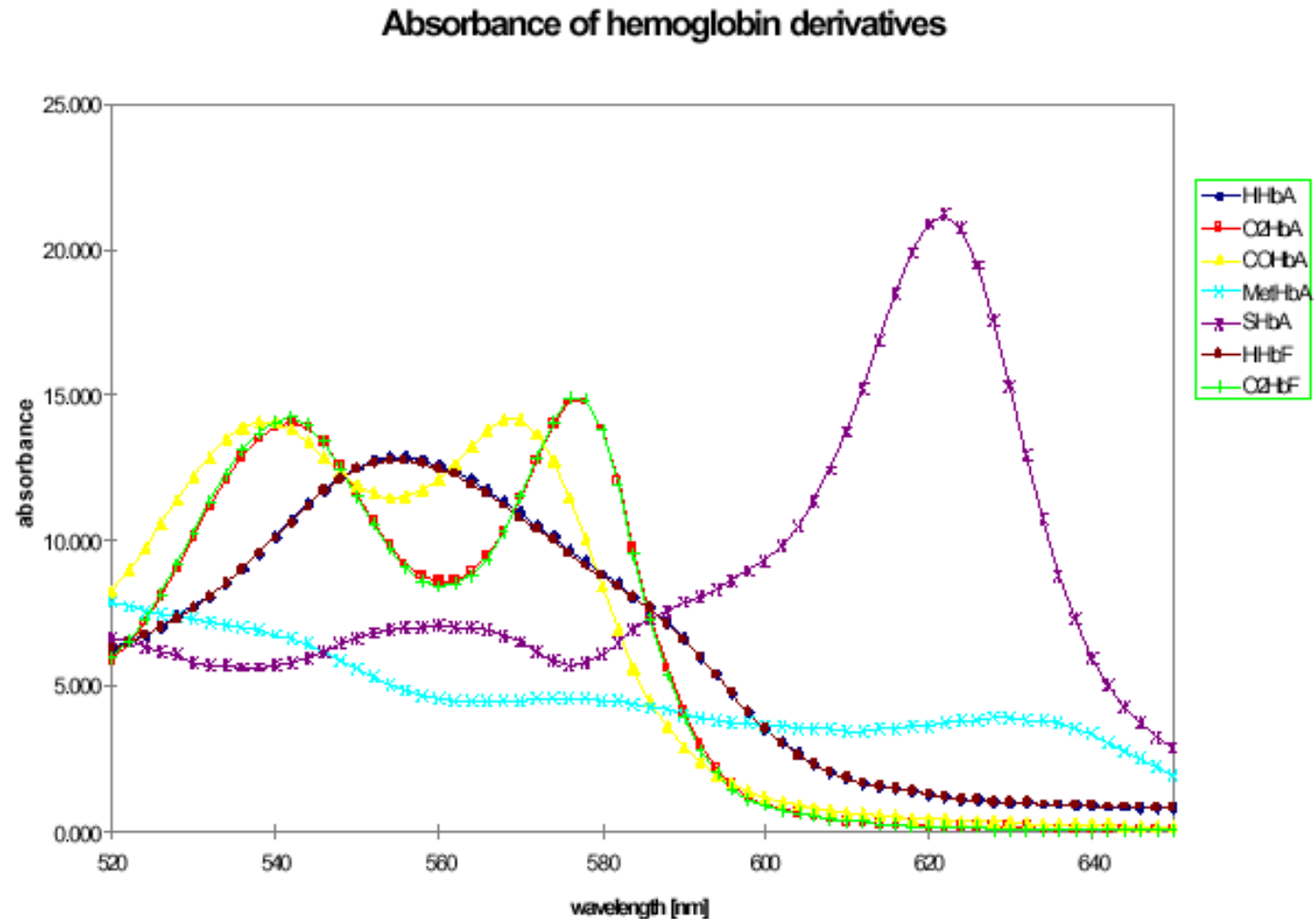
COOX 测量原理

Roche *cobas* 221 polyOxModule



Roche *cobas* 221 PolyOxModule

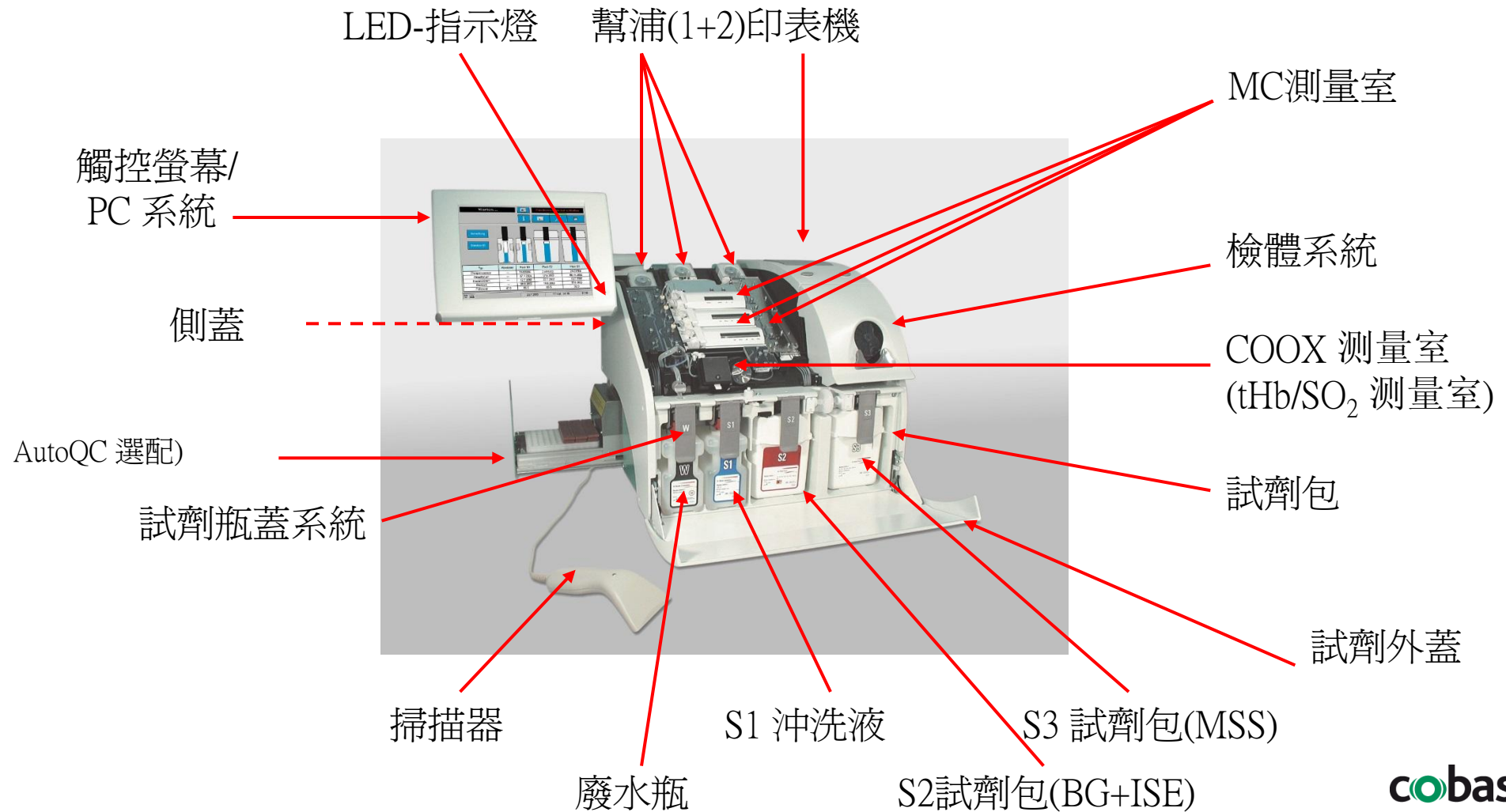
用500—800nm 的連續光譜掃描比色片中的被超音波打碎的血細胞，得到各個波峰，根據波峰的情況換算出各個血紅蛋白的含量



Roche *cobasb* 221

儀器結構

Roche cobas 221 – 儀器結構



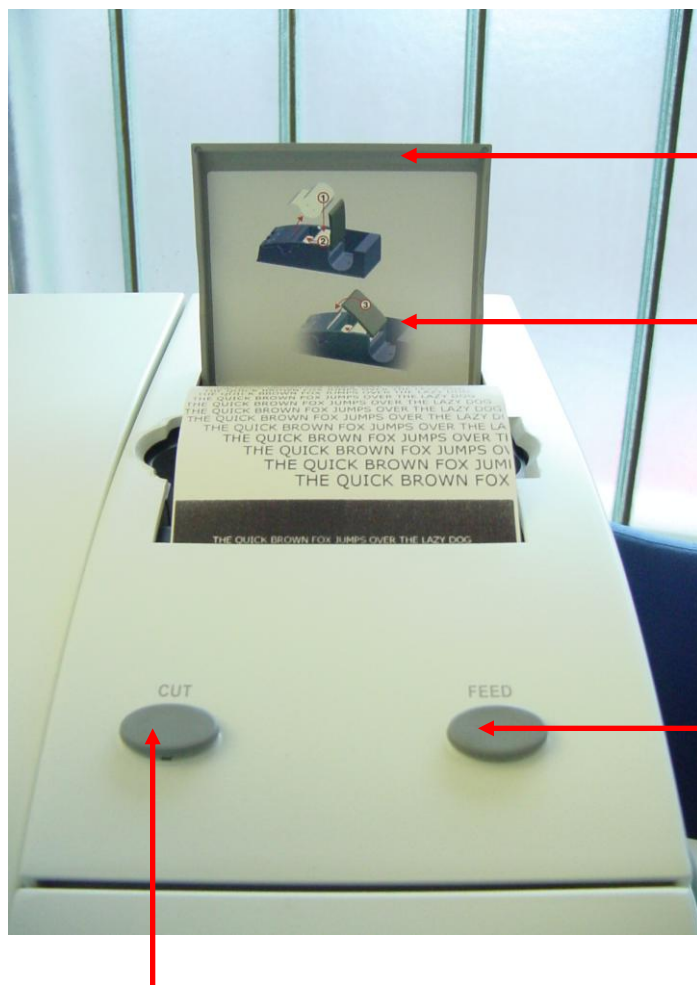
Roche cobas 221 – 觸控螢幕 - PC 系統



型號: TFT LCD flat
規格: 10.4 inch
像素: 640 x 480

使用者介面: 所有訊息會顯示在彩色LCD觸控顯示幕上
PC系統包含一個軟體驅動程式

Roche cobas 221 – 熱感印表機



紙蓋

裝紙釋義圖

進紙鍵

切紙鍵

低噪音熱感印表機

自動裁紙系統

捲紙系統(選配)

精度: 8 點/mm

全圖形: 864點/行

列印速度: 20 mm/sec

紙寬: 111 mm

紙長: 約 50 m

Roche cobas 221 – 測量室



BG/ISE測量室: 測量室蓋, 電極, 電極固定桿

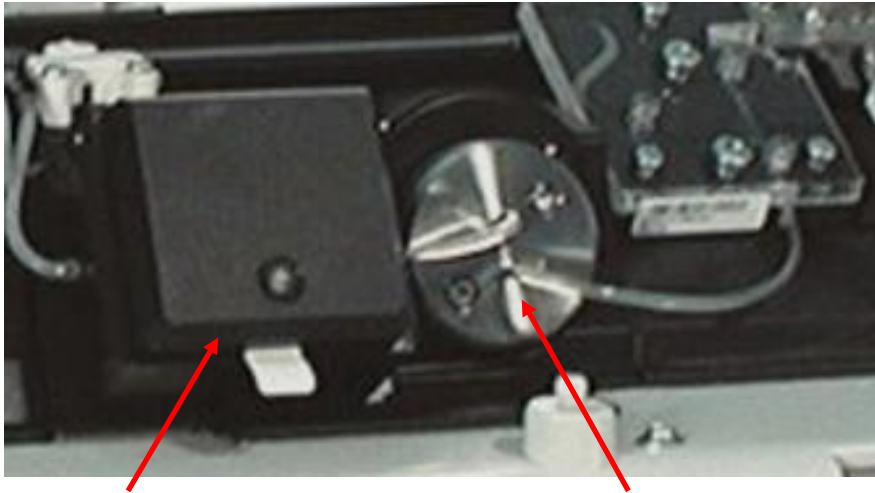
MSS測量室: 測量室蓋, 電極(MSS电极卡), 電極固定桿

測量室視窗

tHb/SO₂ 測量室(cobas b 2215)

COOX 測量室(cobas b 2216)

Roche cobas 221 - COOX 測量室



COOX 模組

超音波產生器



COOX 模組

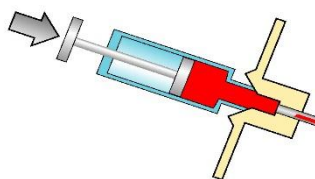
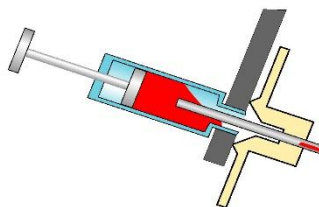
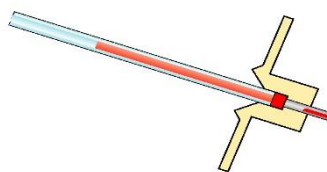
COOX 模組由超音波產生器和 COOX 測量室組成

超音波產生器破壞紅血球細胞

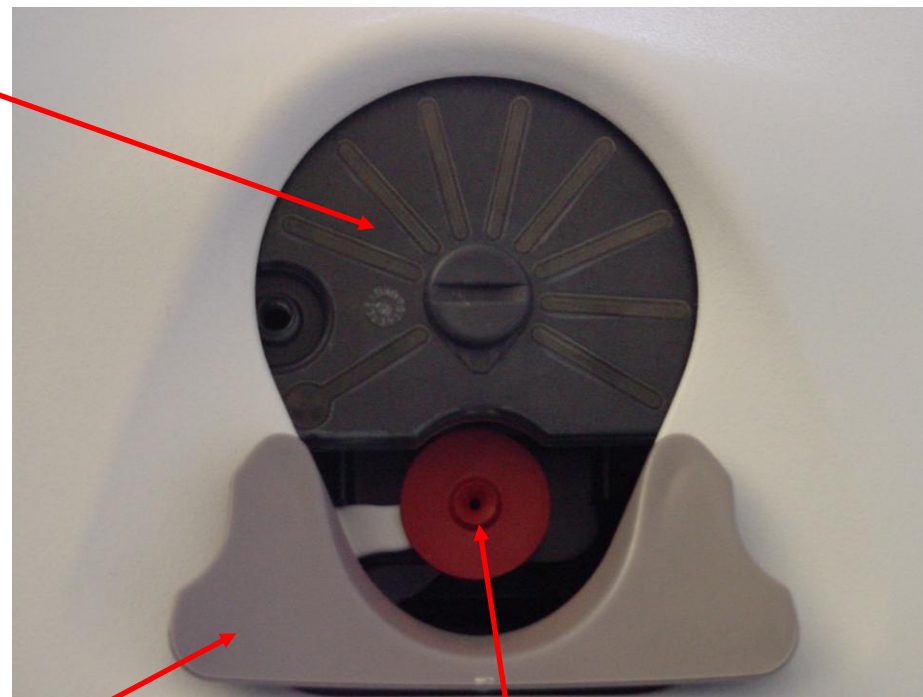
COOX 是利用光譜測量

Roche cobas 221 - 注入系統

檢體通過注入口用毛細管吸入, 注射器吸入, 注射器推入方式



T&D盤



接血盤

檢體注入口

Roche *cobas* 221 – 真空幫浦



負壓沖洗(S1)

壓力感測器



真空防止溢流系統

Roche cobas 221 – 試劑瓶



廢液瓶

S3 試劑包

S1 沖洗液

S2 試劑包

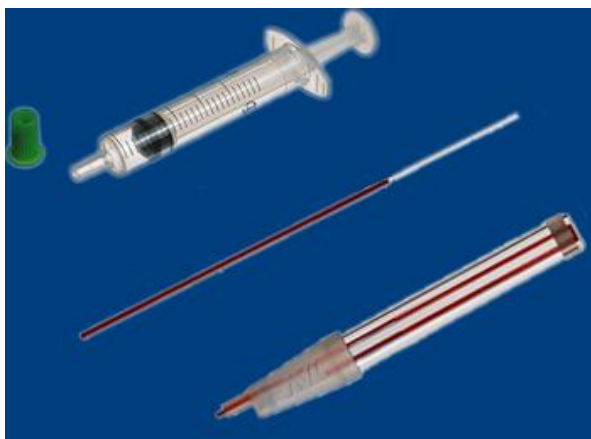
Roche *cobas b221*

測量檢體



Roche *cobas* 221 – 測量

1. 注射器推入檢體
2. 毛細管吸入檢體
3. 注射器吸入檢體



Roche cobas 221 – 測量

注射器推入模式

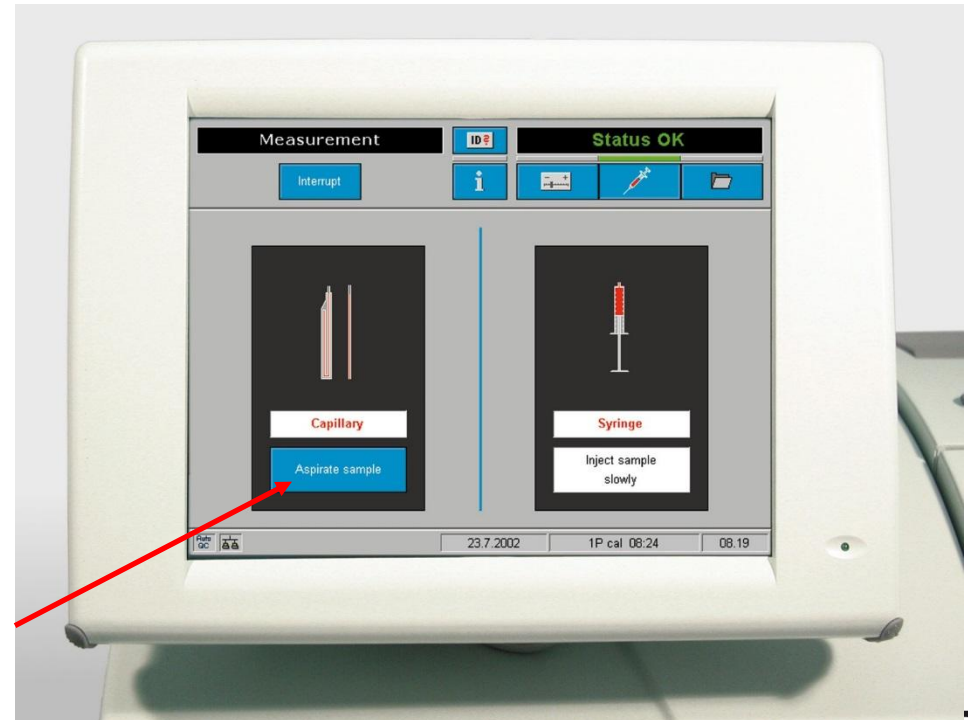
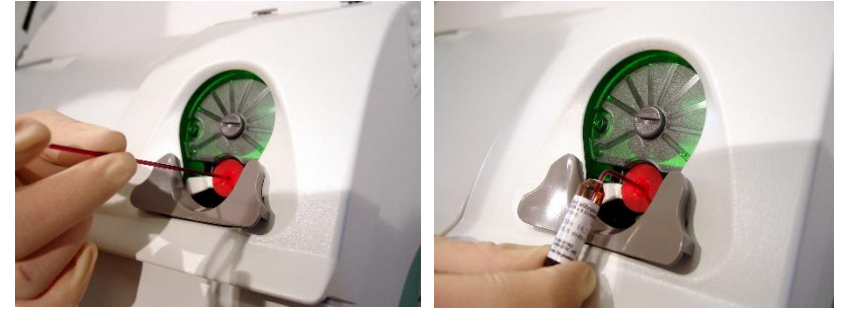
- 將注射器接近注入孔，儀器自動感應到檢體，螢幕出現如下圖
- 緩慢推入檢體，儀器在檢體量足夠後，發出警示音.
- 移開注射器，螢幕出現如下圖：
„Remove sample container “ .
- 測量自動進行



Roche cobas 221 – 測量

毛細管檢體

- 將毛細管或品管液插在注入孔裡
- 按 „Aspirate sample “
- 當儀器出現警示音，螢幕顯示 „Remove sample container “
- 移除毛細管後,儀器自動測量

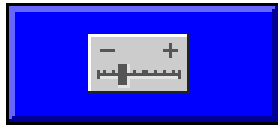


„Aspirate sample “

Roche cobas 221 – 測量

注射器吸入檢體

此一功能在設定模式裡進行設定:

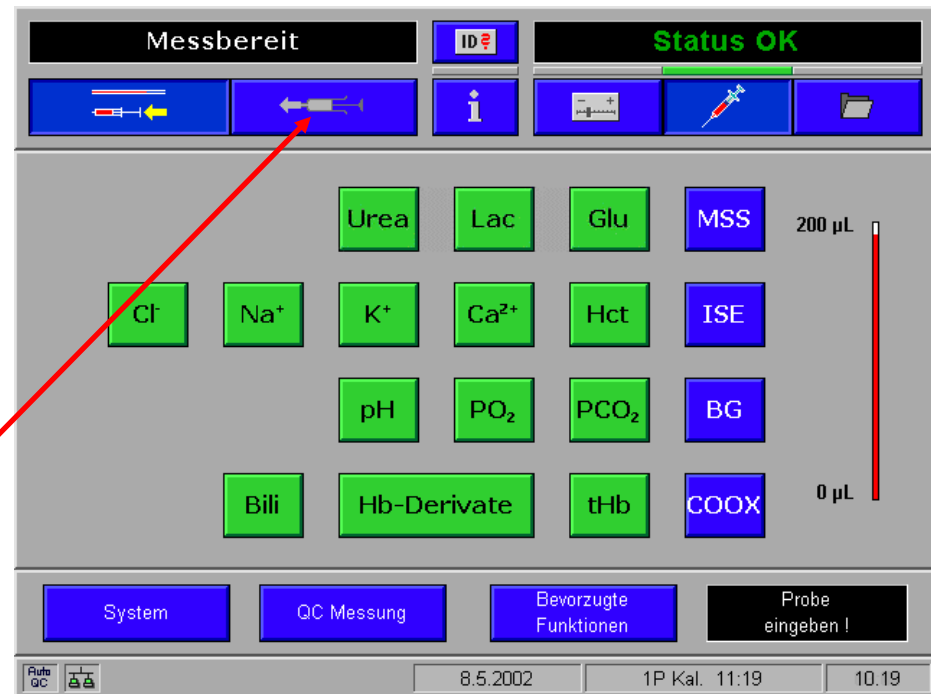


Instrument - Switches - Aspirate from syringe

在 „Ready screen “ 畫面
„Aspirate from syringe “ 出現

- 按 „Aspirate from syringe “ 后
T&D 盤自動旋轉到3號位置

„Aspirate from syringe “



Roche cobas 221 – 測量

- 將注射器緊插在 T&D 3號位置
- 按 „Aspirate sample “
- 儀器自動吸入檢體
- 檢體量足夠後，儀器發出警示音，螢幕顯示 „Remove sample container “
- 移開注射器，儀器開始自動測量



Roche *cobas b221*

品管

Roche cobas b 221 – Quality Control

- Press „Ranges “ and read in the additional barcodes for the target values. The Roche cobas b 221 automatically assigns these.
- The target values can also be entered manually.
Press „Set “ to edit a previously defined material/level combination.

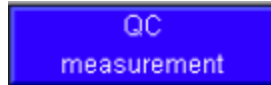
Material	Level	Lot number	Exp. date	Base
AUTO-TROL PLUS B	1	21821301	31.12.2002	Aqueous solution
AUTO-TROL PLUS B	2	21821301	31.12.2002	Aqueous solution
AUTO-TROL PLUS B	3	21821301	31.12.2002	Aqueous solution
AUTO-TROL PLUS B	4	---	---	---

Ranges

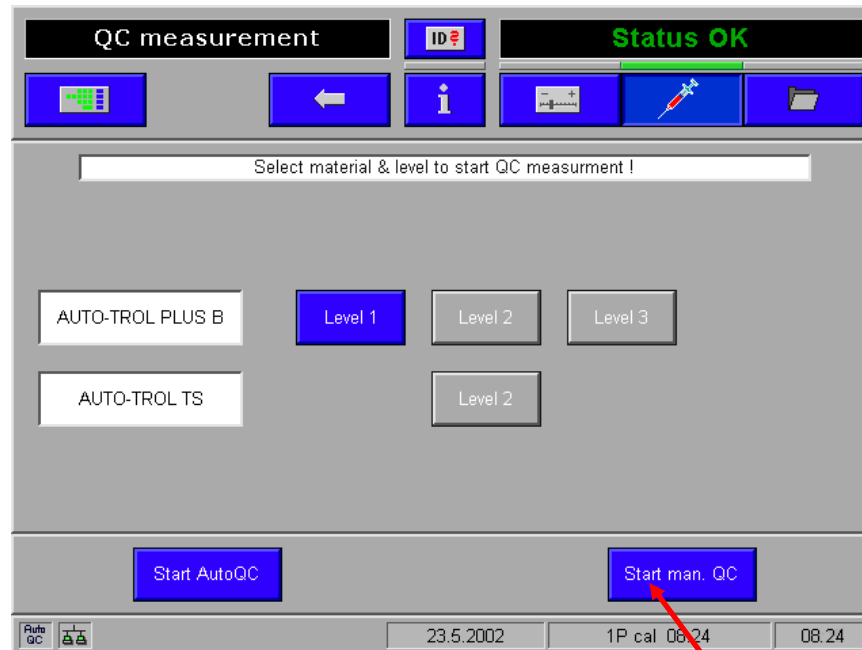
Roche cobas 221 - 品管

手動品管測量

- 按:



“QC measurement”



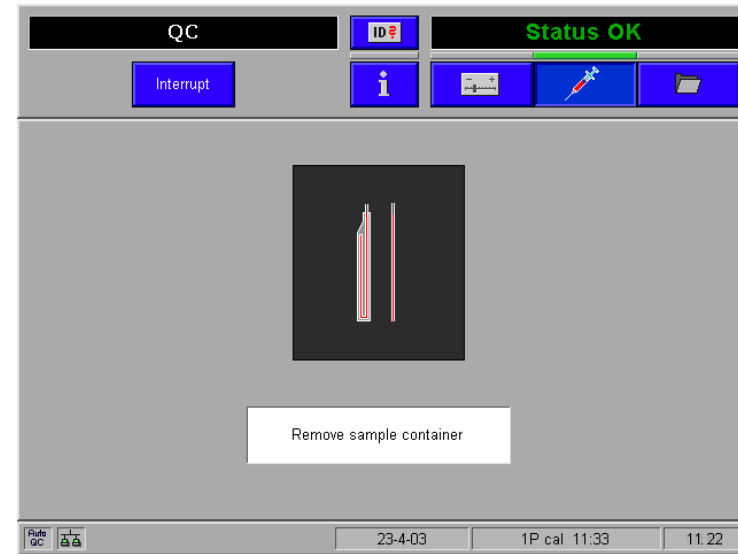
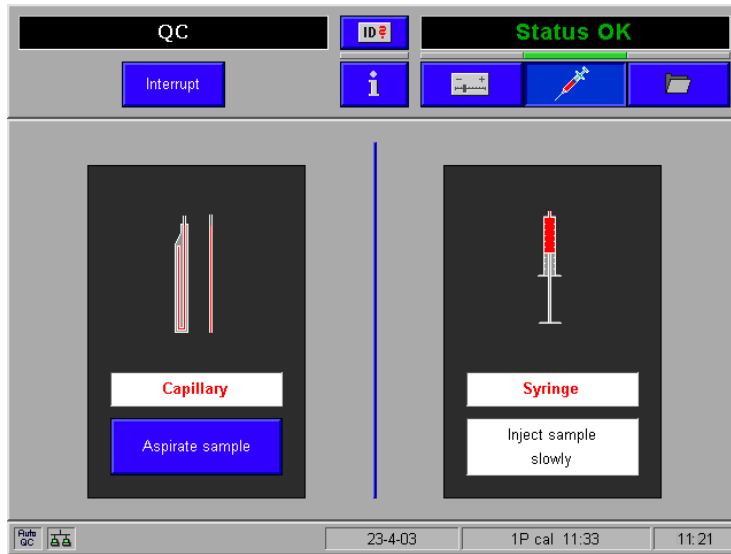
- 選擇相對應的品管物和品管濃度
- 折斷瓶口
- 取出彎管，插入瓶內

• Start man. QC

按:



Roche cobas 221 - 品管



- 按 “Aspirate sample” 按钮
- 當出現 “Remove sample container” 後移開彎管
- 品管液測量開始
- 如果使用者接受結果，儀器將自動列印，並儲存在 QC database 中。

Roche *cobas* b 221 – **AutoQC** Module

6 ampoule mats with 20 ampoules per mat = 120 QC ampoules

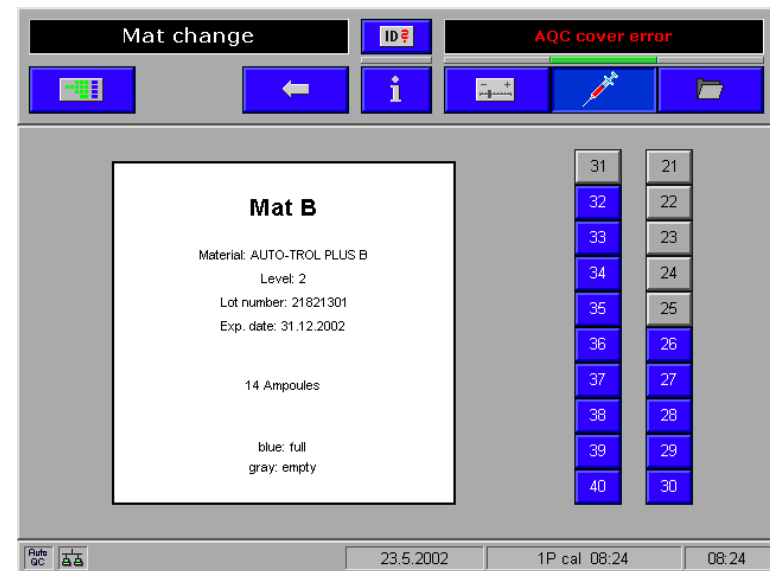
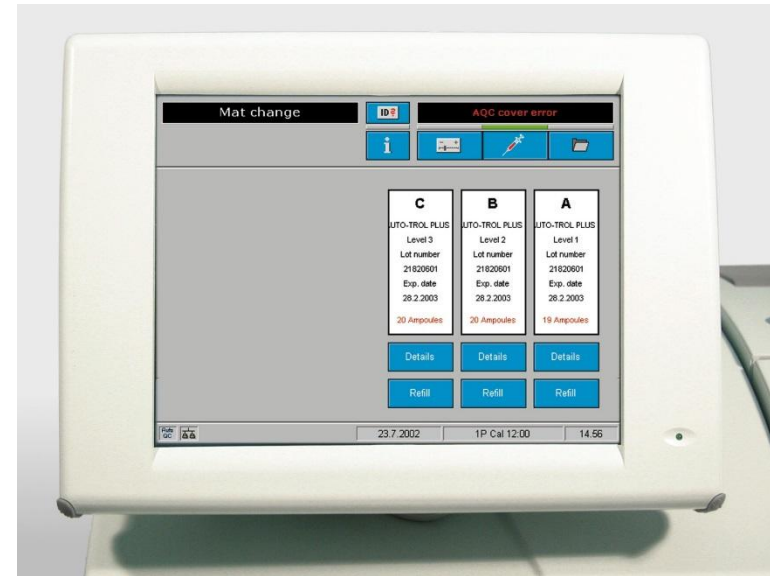


Roche cobas b 221 – Quality Control

Inserting the AutoQC mats

Starting with the top level of the analyzer mode, insert the ampoule mats in the ampoule holder as follows:

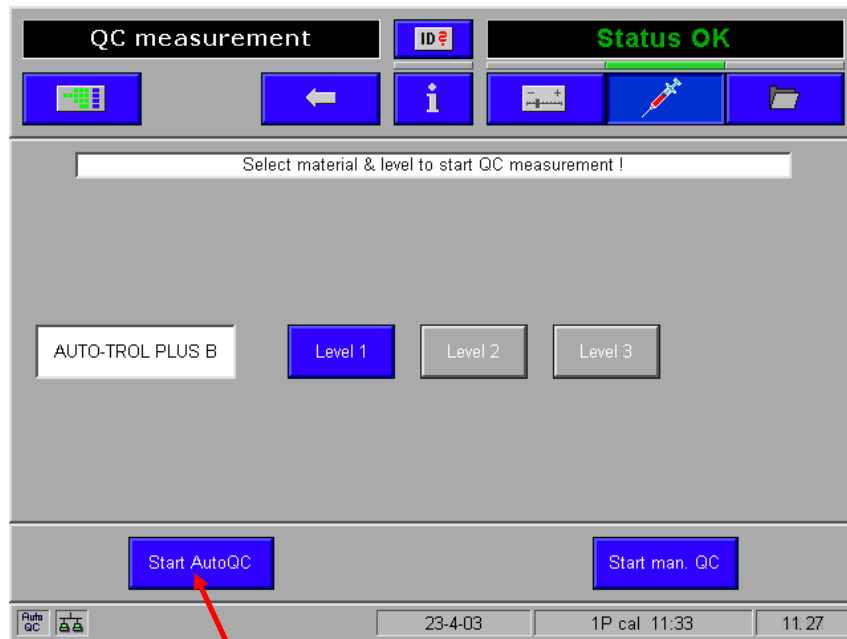
- Pull out the AutoQC drawer.
The following screen appears:



Roche cobas b 221 – Quality Control



AutoQC measurement



Start AutoQC

- The AutoQC measurement can be retrieved programmatically ([Setup -Times & intervals - QC timings](#)) or manually.
- Starting with the top level of the analyzer mode, press „[QC measurement](#)“, activate the corresponding AutoQC material (AUTO-TROL TS+) and the selected level.
- Start the AutoQC measurement by pressing „[Start AutoQC](#)“.

品管注意事項



1. 為了避免開瓶後接觸空氣過久導致pO₂ 數值升高, 於打開ampule 前請先將儀器置於待測QC狀態; 開瓶後必須立即測定。
2. 因手心溫度高, 易使溶入之氣體溢出, 因此, 測定時勿以手心握ampule。
3. 為了避免因人或器械所造成之差異, 儘可能以直接自動吸取方式取樣, 避免以syringe 或其他容器取樣再注入儀器。
4. 品管液放置環境溫度最好為維持在21~23℃之間, 因放置溫度升高會使品管液pO₂ /pCO₂測值下降; 反之放置溫度降低會使品管液pO₂測值上升。

Temperature correction for PCO₂ and PO₂



Parameter/ level(mmHg)	15~17 °C	18~20 °C	21~23°C	24~26°C	27~28 °C
PCO ₂ Level 1	1.62	0.81	0.00	-0.81	-1.49
PO ₂ Level 1	3.96	1.98	0.00	-1.98	-3.63
PO ₂ Level 2	6.89	3.45	0.00	-3.45	-6.32
PO ₂ Level 3	9.53	4.76	0.00	-4.76	-8.73

例:設Level 3 QC儲存溫度為24~26 °C,原PO₂範圍為139.4~159.4mmHg,
需向下修正範圍為(139.4~159.4mmHg)- 4.76mmHg = 134.6~154.6mmHg。

Roche *cobas b221*

保養

Roche cobas 221 – 儀器保養

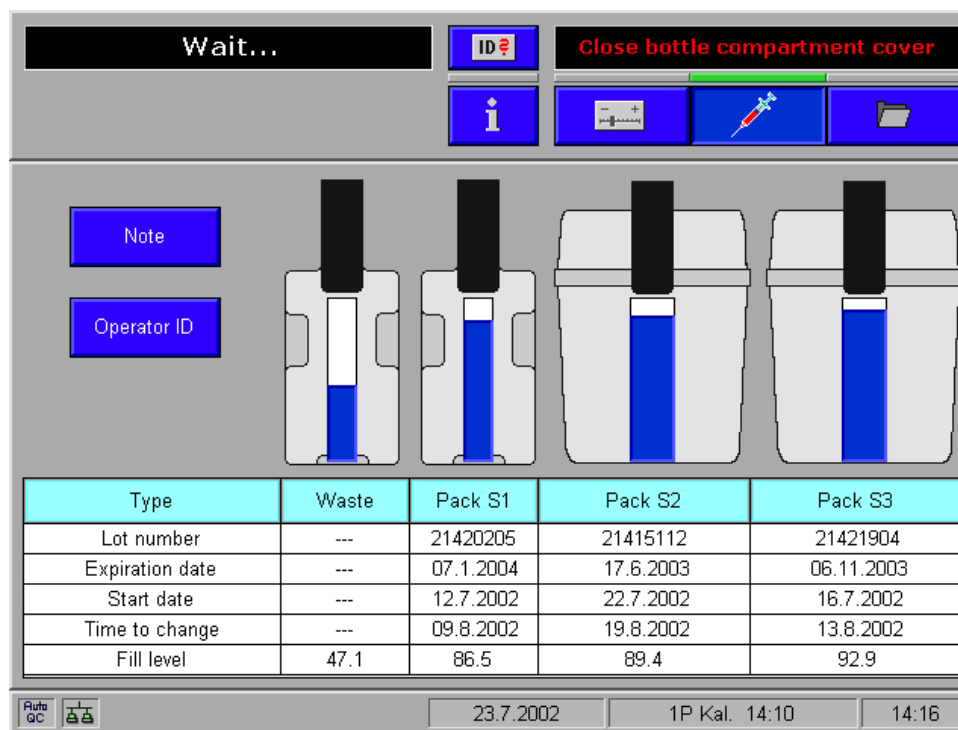


時間	建議	必須完成	儀器程序	備註
每天	檢查試劑液面並更換 檢查熱感紙並更換 清潔儀器表面		進入程序檢查	
每週	清潔注入口部份 清潔螢幕	清潔注入口	進入程序操作	
每3月	清潔T & D轉盤 COOX校正	COOX 校正	進入程序操作	

Roche cobas 221 – 保養－檢查試劑

檢查試劑液面

- 按  按 “Fill levels”



Roche cobas 221 – 保養－清潔注入口

- 進入程序：

System - Wash & cleaning - Clean fill port

- 打開試劑蓋
- 取出接血盤清潔
- 拆下 T&D 轉盤清潔
- 清潔注入口
- 旋轉 90° 拆下注入口，用濕紗布清潔
- 用注入口（做工具）旋轉 T&D 固定螺釘，
拆下 T&D 轉盤清潔



Roche cobas 221 – 保養－廢液瓶

1. 倒空廢液瓶

- 拆下瓶蓋，不能動綠色管
- 倒空廢液瓶
- 旋緊瓶蓋

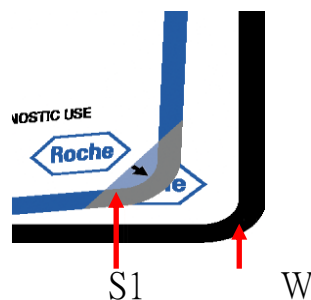


綠色管

2. 使用空S1瓶子當廢液瓶



取下S1試劑標籤



露出“Waste”字樣



“W”標籤圖示

Roche cobas 221 – 保養（不定期）

- 根據檢體執行情況的保養
 - 更換S1，S2，S3試劑，
 - W廢液瓶
 - 清潔測量模組和檢體通道
- 不定期
 - 更換注入口
 - 清潔試劑區
 - 更換熱感紙
 - 更換電極
 - 更換 MSS 電極
 - 清潔測量室





Insert name

cobas IT solutions at the Point of Care

Bringing it all together

Roche Accu-Chek Inform II solution

Quality Control Processes in JCI



- QCP.1.1 The laboratory has a program of external graded **interlaboratory comparison** testing or proficiency testing for analytes for each specialty and subspecialty for which such testing is available.
- QCP.1.2 The laboratory uses a system to **evaluate and correlate the relationship between results** for the same test performed with different methodologies or instruments or at different sites.
- QCP.1.3 The laboratory performs **initial validation** for new instruments and analytical systems to verify that the method(s) will produce accurate and reliable results.
- QCP.1.4 The laboratory validates electronic or internal monitoring systems prior to using them for **routine quality control**.
- QCP.1.6 The quality control processes of the laboratory include a coordinated review of patient results, quality control results, and instrument function checks.

Point of Care Checklist in CAP



Diagnostics

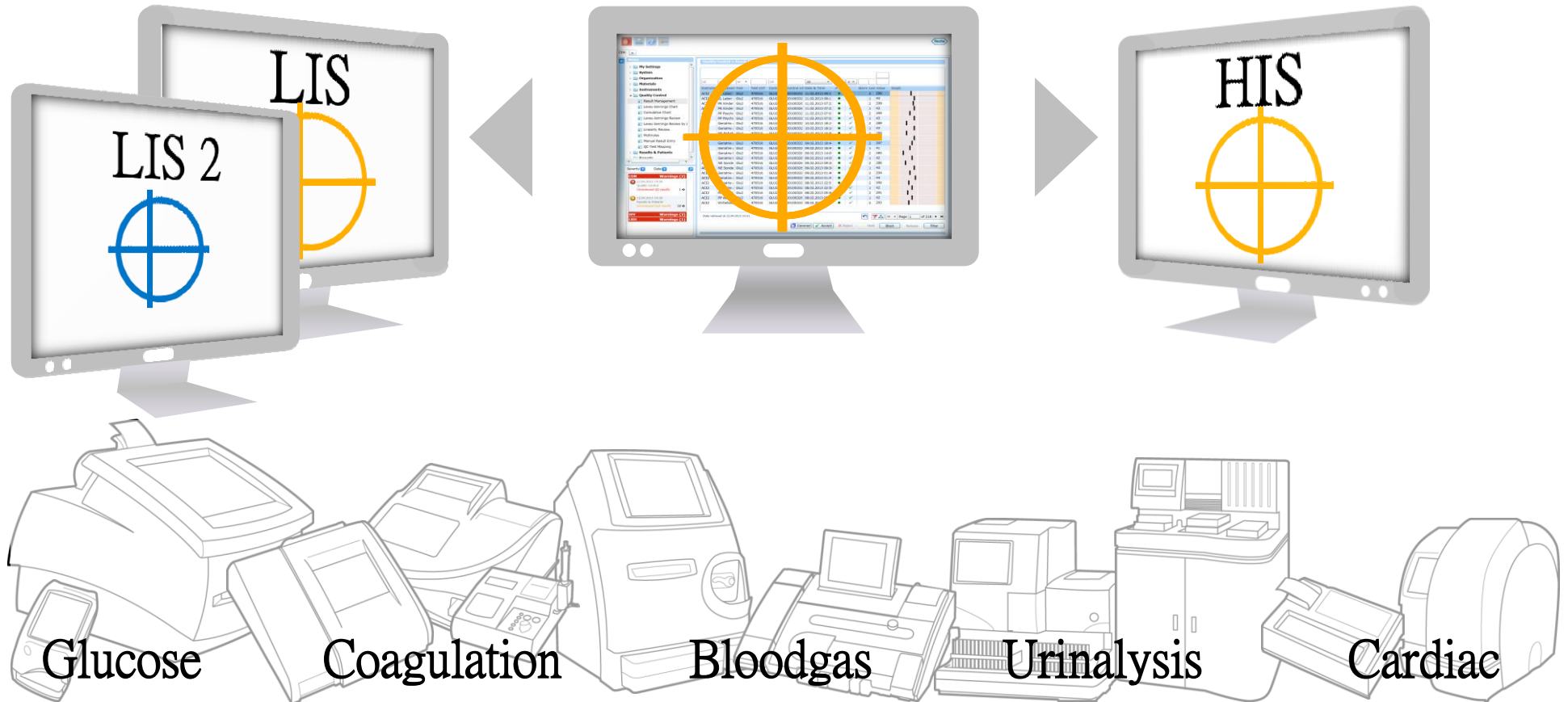
- POC.03250 PT Integration Routine Workload
- POC.03275 PT Evaluation
- POC.03366 PT Interlaboratory Communication
- POC.03550 Organizational Chart
- POC.03700 Unusual Laboratory Results
- POC.03800 Troubleshooting Responsibilities

cobas IT solutions at the Point of Care

Centralizes decentralization



Diagnostics

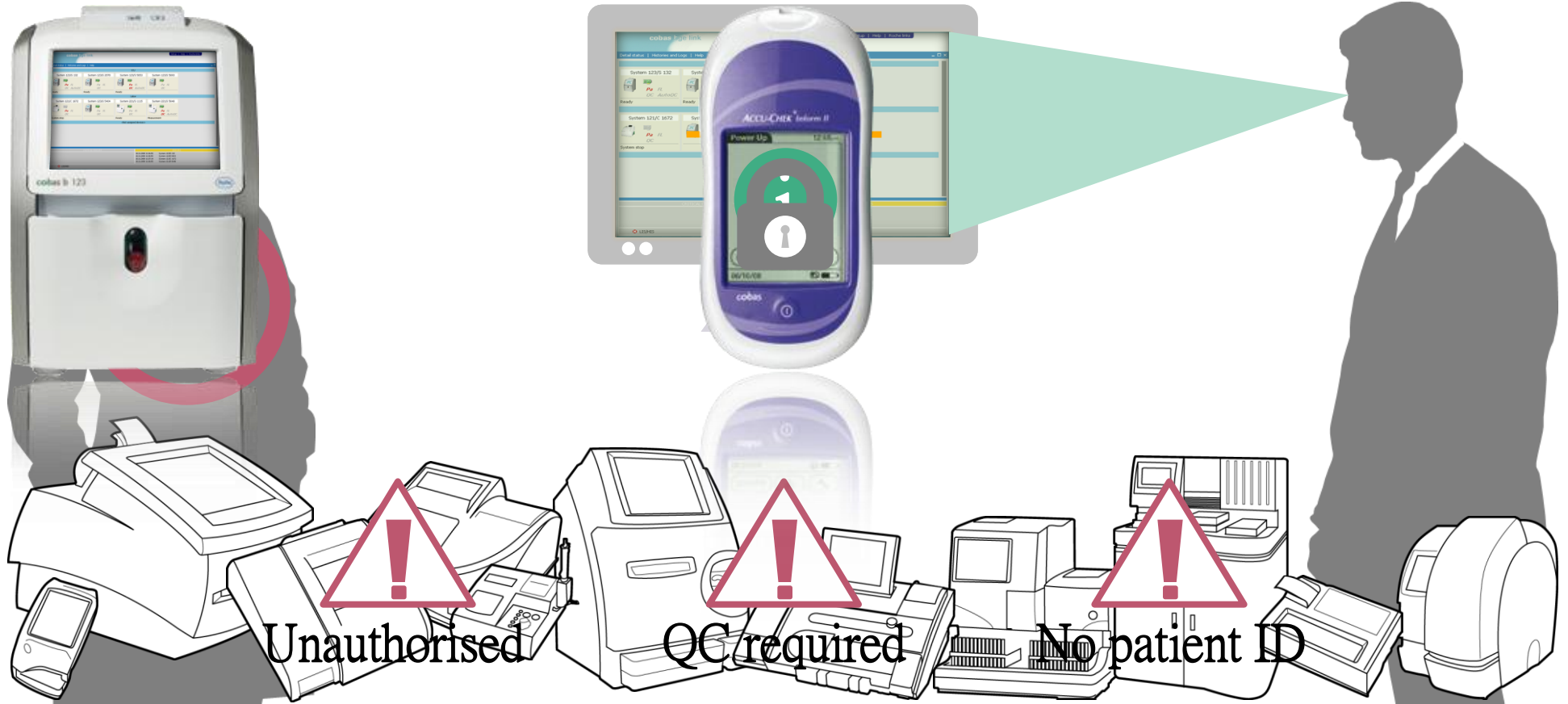


cobas IT solutions at the Point of Care

The comprehensive POC management solution



Diagnostics



cobas point-of-care solutions and compliance

Manages compliance... keeps you informed and safe



Device



User



Material lot



QC



Training status



JCAHO



JCI



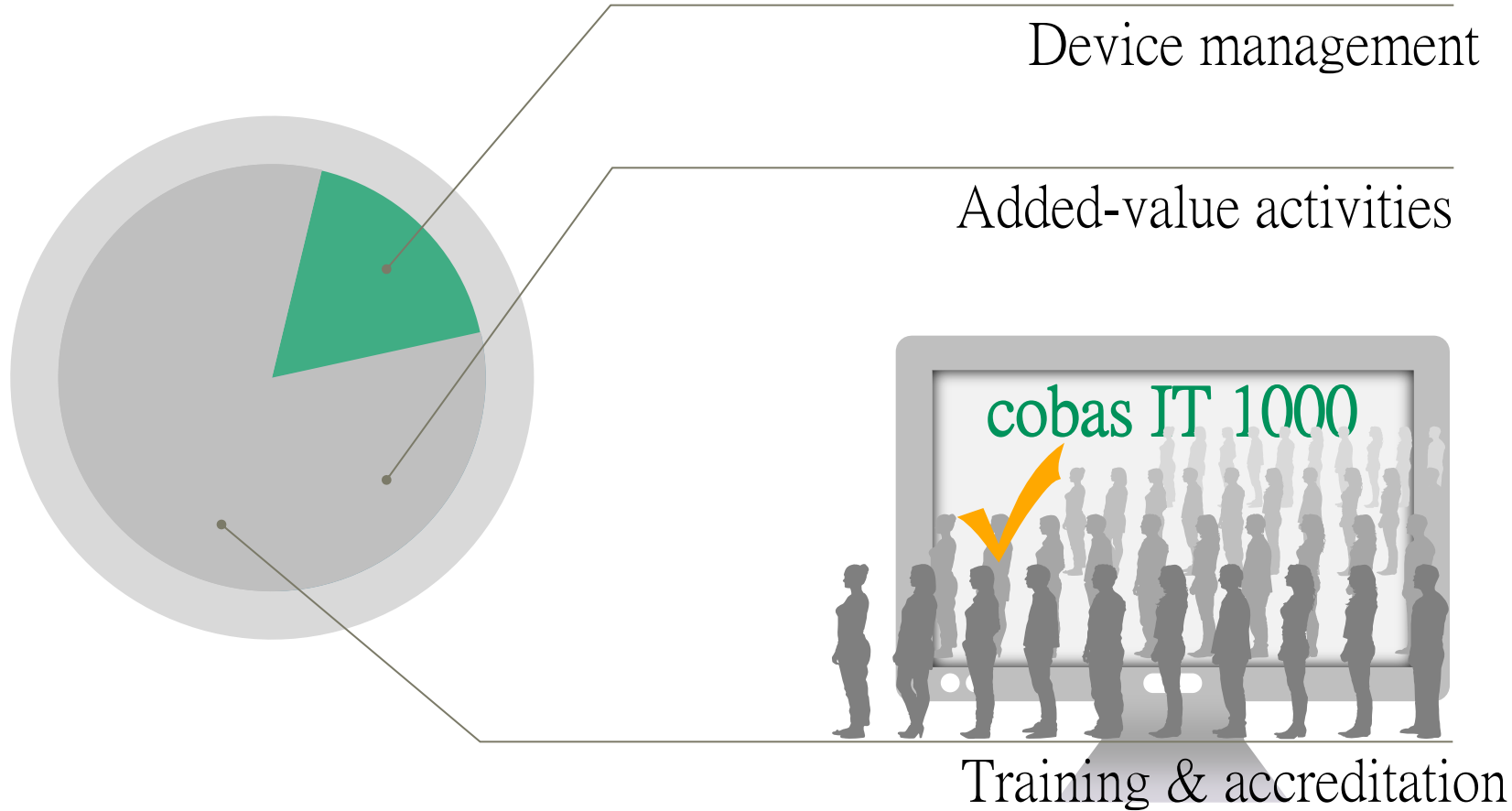
CAP



The challenge of user management in POC



Diagnostics



Automated user certification

Fully automated user certification...THE time saver for coordinators



User training with cobas academy

Efficient online user training: customizable to your needs



Diagnostics



Online training



Face to Time-saving



Automated QC Lot Management

Further contributing to result security

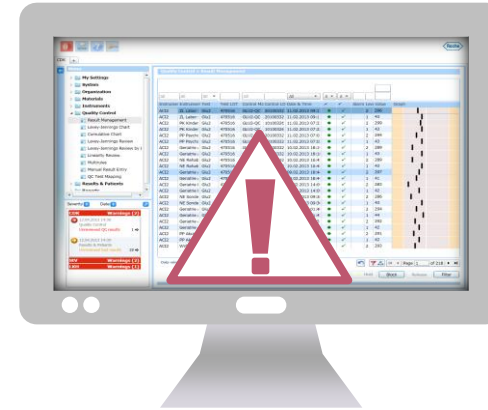
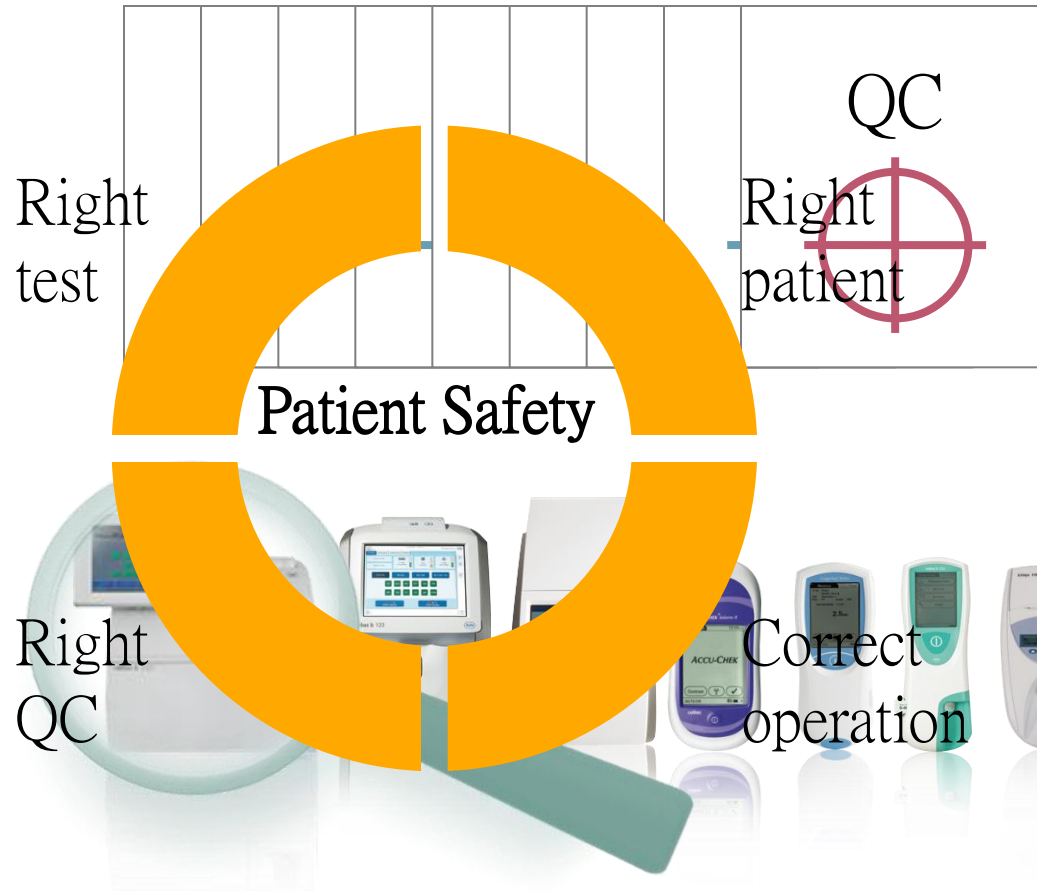


Diagnostics



Result security

The right test on the right patient with the right QC

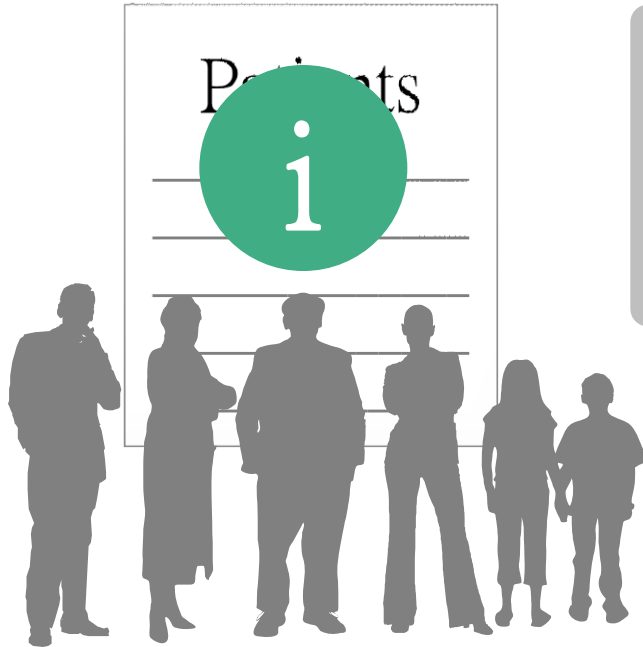


Enhanced patient ID communication

For result security and patient safety



Diagnostics



rework/
Risks



Proven performance

Known to work



Diagnostics



820 installed cobas IT 1000 servers

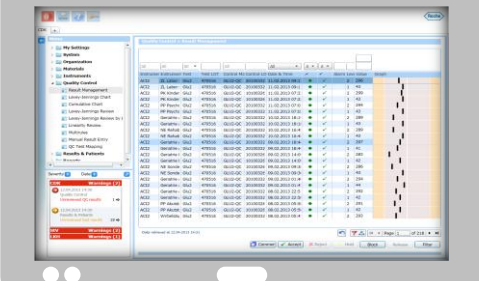
70,000 connected instruments

Architected for scale and scope

Third party drivers for open connectivity

Fits your individual needs



Abaxis Piccolo Xpress	HemoCue Glu201 DM	IL GEM Premier 4000	LifeSign Dxpress POC	Radiometer ABL500 series	Radiometer ABL800 series	Siemens RapidLab 1200
Abbott i-STAT CDs	HemoCue Glu201 DM RT	Hemochron Jr. Signature	Medtronic ACT Plus	Radiometer ABL600 series	Radiometer ABL90 Flex	Siemens RapidPoint 400
ABX e-SAT	HemoCue Hb 201 DM				Radiometer AQT90 Flex	Siemens DCA Vantage
ABX Micros CRP	IL GEM Premier 3000				ROTEM delta	Siemens Clinitek Status
Axis-shield Afinion AS1000	IL GEM OPL	Hemochron Jr. Signature+	OPTI Medical OPTI CCA	Radiometer ABL700 series	Siemens CLINITEK Status	Sysmex KX-21N
Biosite Triage	IL GEM PCL Plus	Hemochron Signature Elite	Orion QuikRead go	Radiometer ABL80 Flex	Siemens RapidLab 800	Sysmex pocH-100i

Thanks for your attention ~

