RAPIDLab 348EX

System

Operator's Guide

10698292 Rev. F, 2025-04

CE

SIEMENS

This Operator's Guide provides the instruction about the products mentioned below.

Product Name	SMN	
Ready Sensor - Sodium (Na^+)	10312557	
Ready Sensor - pH	10312556	
Ready Sensor - pO_2	10324408	
Ready Sensor - Hct	10309783	
Ready Sensor - pCO_2	10317498	
Ready Sensor - Calcium (Ca^{++})	10315922	
Ready Sensor - Potassium (K^+)	10327404	
Ready Sensor - Reference (Ref)[a]	10323084	
Ready Sensor - Chloride (Cl^-)[a]	10330133	
Hct Slope	10309776	CE 0197
Ready Sensor - Ref Refill[a]	10320458	
RAPIDLab 348EX 6.8/7.3 Buffer	10309757	
Gas Cartridge Pack[b]	10309768	
RL348EX Starter Kit + Ca ROW	10844682	
RL348EX Starter Kit + Cl ROW	10844683	
RL348EX Starter Kit BG ROW	10844684	
RAPIDLab Reference Electrode Fill	10311081	
RAPIDLab 348EX pH Electrode Fill	10311046	
RAPIDLab 348EX $Na^+/K^+/Ca^{++}/Cl^-$ Electrode Fill	10311047	
Ready Sensor - Reference Inner[a]	10329947	
RAPIDLab 348EX 6.8/7.3 Buffer (Japan)	10336723	
RAPIDLab 348EX Wash	10309756	
Deproteinizer	10309775	
Conditioner Kit	10311078	
MULTICAP capillary tubes, 50 x 100 µl[a]	10323539	
MULTICAP capillary tubes, 500 x 100 µl[a]	10322912	CE
Caps for 140 µl capillary tubes, pack of 100	10311054	
Blood Collection Capillaries Multicap[a]	10311005	
MULTICAP capillary tubes, 50 x 140 µl	10314796	
Plastic capillary tube, 500 x 140 µl[a]	10313226	
Plastic capillary tube, 50 x 100 µl[a]	10313252	
Plastic capillary tube, 500 x100 µl[a]	10322986	

Product Name	SMN	
Plastic capillary tube, 500 x 175 µl[a]	10316361	
Plastic capillary tube, 50 x 140 µl[a]	10320937	
Plastic capillary tube, 50 x 175 µl[a]	10324363	
Capillary Caps	10328655	
Blood Collection Capillaries Multicap 50 x 175µL Pack[a]	10325868	
Blood Collection Capillaries Multicap[a]	10315378	
Test/Blank sensor $K^+/Ca^{++}/Cl^-$ (TB3)	10311665	CE
Test/Blank sensor ref (TB5)	10327492	
RAPIDLab 348EX System	10844678	
Wash Pack (Japan Only)	10329872	
MULTICAP blood collection kit, containing 100 x 60 µl capillary tubes and 200 caps	10314213	
Adaptors for capillaries, pack of 100	10330785	
Capillary Caps	10311053	
Blood Collection Capillaries for pH/Blood Gas	10310990	
Blood Collection Capillary Tubes 100µl	10321712	
Blood Collection Capillary Tubes 140µl	10327012	
Blood Collection Capillary Tubes 140µl	10327283	

a. Indicates Insert available with basic instructions about the product.

b. Indicates product with its own Instructions for Use.

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The information in this operator's guide was correct at the time of printing. However, Siemens Healthcare Diagnostics continues to improve products and reserves the right to change specifications, equipment, and maintenance procedures at any time without notice.

If the system is used in a manner differently from that specified by Siemens Healthcare Diagnostics, the protection provided by the equipment may be impaired. See warning and hazard statements.

Contents

Appendix A: Concepts and Reference Information

Using This Guide

Who Should Use This Guide

The *RAPIDLab 348EX System Operator's Guide* provides information for clinical laboratory professionals who use the system, specifically, for:

- Routine operators

  Medical or laboratory personnel who use the system to analyze patient and QC samples, to view and print results, and to perform routine maintenance.

- System supervisors

  Laboratory supervisors or designated key operators who perform Setup functions, monitor the use of the system, and assist with troubleshooting and maintenance when necessary.

Conventions Used in this Manual

This manual uses the following text and symbol conventions.

Convention	Description
	Warning statements provide information about conditions that may cause injury to personnel.
	Caution statements provide information about conditions that may cause product damage.
	Biohazard statements alert you to potentially biohazardous conditions.
Note	**Note** statements alert you to important information that requires your attention.
Bold	**Bold** type within text indicates a user selection, such as the path to a particular screen or the name of a button on the touch screen; for example, **Calibration**.
>	A separator in the navigational path leading to a particular screen; for example, **Ready > Settings > System Setup > Print Setup Report**.

Understanding the Symbols

Certain symbols appear on the exterior of the system or on the packaging. The symbols on the system show you the location of certain components and may contain warnings for proper operation. The symbols on the system or packaging provide you with other important information. For a complete list of the symbols used in this guide, see *Appendix G, Symbols*.

1 Safety Information

Read This First

Your personal safety is of paramount importance, therefore please read this section before operating the RAPIDLab 348EX system. This section summarizes the following procedures for protecting yourself from biohazards, laser hazards, and electrical hazards:

General Safety Information

WARNING

Do not use an ungrounded outlet with this equipment. The system is designed to be grounded through the power supply lead (line cord) for safe operation. For the safety of operating personnel and optimum performance make sure that the instrument is connected only to a grounded power outlet that has an effective earth connection. If you use an adapter, ensure that the grounding wire is properly connected to a permanent ground.

The system has no internal user-replaceable parts. Do not remove the back cover from the system.

Siemens Healthcare Diagnostics and its authorized representatives are responsible for the safety, reliability and performance of the RAPIDLab 348EX system only if:

- Assembly operations, extensions, re-adjustments, modifications or repairs are carried out only by persons authorized by them.
- The electrical installation of the relevant room complies with IEC requirements or the local regulatory code.

- The equipment is used in accordance with the instructions for use, and by persons knowledgeable in safe laboratory practices.

The RAPIDLab 348EX system is classed as IEC Type B equipment (Class 1 equipment providing an adequate degree of protection against electric shocks particularly regarding allowable leakage currents and reliability of the protective earth connection).

Agency Standards

The system is not designed for use in an environment containing a flammable anaesthetic mixture with air, oxygen or nitrous oxide and is not designed to give protection against the ingress of liquids.

The RL348EX instrument has been tested for safety by TÜV SÜD, a national certification body, for conformity to global markets, including Canada, US, and Europe.

Safety Certifications

For information on safety certifications, see the Declaration of Conformity (DoC). For a DoC, contact your local technical provider or distributor.

Electromagnetic Compatibility (EMC)

For information on electromagnetic compatibility, see the Declaration of Conformity (DoC). For a DoC, contact your local technical provider or distributor.

WARNING

Protection is impaired if used in a manner not specified by the manufacturer.

Protecting Yourself from Biohazards

This section summarizes the established guidelines for handling laboratory biohazards. The summary is based on the guidelines developed by the National Institute of Health (NIH) and Centers for Disease Control (CDC), the guidelines in CLSI Document M29-A3, *Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline - Third Edition*. Wayne, PA: Clinical and Laboratory Standards Institute.

Use this summary for general information only. It is not intended to replace or supplement your laboratory or hospital biohazard control procedures.

By definition, a biohazardous condition is a situation involving infectious agents that are biological in nature, such as the hepatitis B virus (HBV), the human immunodeficiency virus (HIV), and the tuberculosis bacterium. These infectious agents may be present in human blood and blood products and in other body fluids.

The following are the major sources of contamination when handling potentially infectious agents:

- Needlesticks
- Hand-to-mouth contact
- Hand-to-eye contact
- Direct contact with superficial cuts, open wounds, and other skin conditions that may permit absorption into subcutaneous skin layers
- Splashes or aerosol contact with skin and eyes

To prevent accidental contamination in a clinical laboratory, strictly adhere to the following procedures:

- Wear gloves while servicing parts of the system that have contact with body fluids such as urine or whole blood.
- Wash your hands before going from a contaminated area to a noncontaminated area, or when you remove or change gloves.
- Perform procedures carefully to minimize aerosol formation.
- Wear facial protection when splatter or aerosol formation are possible.
- Wear personal protective equipment such as safety glasses, gloves, lab coats or aprons when working with possible biohazard contaminants.
- Keep your hands away from your face.
- Cover all superficial cuts and wounds before starting any work.
- Dispose of contaminated materials according to your laboratory's biohazard control procedures.
- Keep your work area disinfected.
- Disinfect tools and other items that have been near any part of the system sample path or waste area with 10% v/v bleach.
- Do not eat, drink, smoke, or apply cosmetics or contact lenses while in the laboratory.
- Do not mouth pipet any liquid, including water.
- Do not place tools or any other items in your mouth.
- Do not use the biohazard sink for personal cleaning such as rinsing coffee cups or washing hands.

- Do not recap, purposely bend, cut, break, remove from disposable syringes, or otherwise manipulate needles by hand. Needlestick injuries may result.

References

1. Centers for Disease Control. *Update: Universal precautions for prevention of transmission of human immunodeficiency virus, hepatitis B virus and other bloodborne pathogens in healthcare settings*. 1988. MMWR, 37:377–382, 387, 388.
2. Clinical and Laboratory Standards Institute (formerly NCCLS). *Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline - Third Edition*. Wayne, PA: Clinical and Laboratory Standards Institute; 2005. CLSI Document M29-A3. [ISBN 1-56238-567-4].
3. Federal Occupational Safety and Health Administration. Bloodborne Pathogens Standard. 29 CFR 1910. 1030.

Operating Precautions

- The system is designed to be left connected to an AC power supply. To prevent damage to the instrument, before powering off the system, whether by the power switch or by disconnecting the power cord, perform the procedures in *Shutting Down the System,* page 121. Do not leave it switched off for long periods.
- Never turn the pump rotors counterclockwise. If the system detects a bubble, move the sample forward until it is underneath all the sensors and no air bubbles are beneath the sensors.
- Use Siemens collection devices (if available) or alternative manufacturer collection devices (both syringes and capillaries), may be used on the Siemens systems, and we recommend electrolyte-balanced lithium heparin as the preferred anticoagulant.
- Siemens recommends the use of Siemens-approved QC materials.
- When sampling from syringes, position the probe to obtain the most representative sample. Do not allow the probe tip to touch the syringe plunger. Obstructing the probe tip can cause sampling faults, and, in extreme cases, calibration instability.

  If you suspect the probe tip was obstructed during sampling, we recommend cancelling the sample analysis and calibrating the system. See *Calibrating Your System,* page 63.

- Do not release the measurement block catch unless the instrument has been stopped using the STOP SYSTEM routine. See *Stopping the System,* page 84.
- Carry out routine maintenance at the intervals stated in *Section 7, Maintenance*.
- Ensure that the drip tray is always in place and is correctly connected.
- When working with dialysis fluid, do not measure the acidic component of bicarbonate-based dialysis fluid.
- Handle all samples as if they contain pathogenic organisms. Always wear gloves when handling samples and waste materials.
- Take care when opening ampules. Use ampule breakers to protect your fingers.
- Make sure that before handling the component parts of the system (such as the probe, sensors, measurement block, pump tubing and waste bottle) you have used the Disinfect routine, see *Section 7, Maintenance*. Always wear gloves when carrying out any maintenance to the system.
- Siemens Conditioner contains 0.1M ammonium bifluoride (ammonium hydrogen difluoride) which is toxic if swallowed and will cause burns if it comes into contact with the skin. In case of contact with eyes rinse immediately with plenty of water and seek expert medical advice. Clean spillages immediately and wash with plenty of water.
- Ensure that the manufacturer's directions for use are followed when using disinfectant.
- The system weighs approximately 10 kg (22 lb). Observe safe lifting procedures.
- Do not move the system with the reagent and waste bottles in place.

Using and Replacing Reagents and Supplies

- Use only Siemens reagents and supplies with the system.
- Do not use reagents after the expiry date shown on the label. Do not use 7.382 and 6.838 buffer for longer than 21 days after opening.
- Do not decant solutions from one bottle to another, as this can cause contamination.
- Agitate the Buffer Pack daily, to incorporate any solution that may have condensed on the inside surface of the bottles.
- It is advisable to dispose of the waste daily and add approximately 10 mL of disinfectant or sodium hypochlorite to the bottle.

- When replacing the Buffer Pack or Wash bottle, always remove the waste bottle and put the empty 7.3 Buffer or Wash bottle in its place. Siemens recommends that you put approximately 10 mL of disinfectant or sodium hypochlorite into the empty bottle before placing it in position as the new waste bottle.

Handling Compressed Gas Cartridges

Compressed gas cartridges require careful handling. To prevent damage and possible personal injury, observe the following precautions:

- Never drop cartridges, allow them to strike each other or subject them to other strong shocks.
- Never tamper with the cartridge valves.
- Use these gases for the calibration of clinical and research instrumentation only. (US Law prohibits dispensing these gases for drug use).
- The contents are under pressure. Do not puncture cartridges.
- Do not use or store near heat or open flame.
- Do not expose cartridges to temperatures above 54°C (130°F) as this may cause the contents to vent or explode.
- Never throw cartridges into fire or incinerators. Dispose of the cartridges according to your laboratory protocol.

Protecting Yourself from the Barcode Reader Beam

- Never look directly at the beam of a hand-held barcode reader.
- Never point the scanner at another person.
- Do not look at the reflection of the beam from a shiny surface.

Protecting Yourself from Electrical Hazards

- Do not operate the system in the presence of flammable anesthetic mixture with air, O_2, or nitrous oxide because of the risk of explosion in such an environment.
- The system uses a grounded external power cord for connection to a grounded electrical outlet.The system has no internal user-replaceable parts. Do not remove the back cover from the system.

Global Harmonized System of Classification and Labeling of Chemicals

RAPIDLab 348EX System

Introduction

As of June 2015, all Siemens Healthcare Diagnostic products, assays in particular, will transition to the new Globally Harmonized System of Classification and Labeling of Chemicals (GHS) based-classification system, the internationally agreed-upon system of chemical classification and hazard communication through labeling and Safety Data Sheets (SDS).

In order to comply with the GHS requirements, assay IFUs and the assay packaging and labeling now include the following GHS elements:

- New hazard symbology (pictograms) – appears on the component labeling, carton/box labeling, and in the assay Instructions for Use.
- New hazard signal words (e.g., Warning) for some products – appears on the assay Instructions for Use.
- New hazard statements and associated H codes—indicate the physical, health, and environmental hazards and appear in the assay Instructions for Use.
- New precautionary statements and associated P codes—indicate prevention, response, storage, and disposal guidance and appear in the assay Instructions for Use.

Note that some products that were considered hazardous under the old system will not be hazardous under the new GHS system, and vice versa.

As Siemens implements the new hazard classification system, you may see a mix of the previous and new hazard-classification systems among the component label, carton/box label, and IFU.

This addendum provides GHS information for the following parts for the RAPIDLab 348EX System.

GHS Information

RAPIDLab 348EX Reagent GHS Information

SMN	Reagent Name	Pictogram	Signal word	H Codes	P Codes	Offending Chemicals	Supplemental
10309757	RAPIDLab 348EX 6.8/7.3 Buffer	Slope Standard - Exclaim	Slope Standard - Warning	Slope Standard - H317	Slope Standard - P280, P302+P352, P333+P313, P362+P364	Slope Standard - reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)	Calibration Standard - Contains reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1). May produce an allergic reaction.
10311078	Conditioner Kit	Electrode Conditioning Unit Dose Container - Exclaim	Electrode Conditioning Unit Dose Container - Warning	Electrode Conditioning Unit Dose Container - H319, H315	Electrode Conditioning Unit Dose Container - P264, P280, P337+P313	Electrode Conditioning Unit Dose Container - Ammonium bifluoride	None
10309775	Deproteinizer, Pack of 10 UDC	Pepsin Vial - Health Hazard	Pepsin Vial - Danger	Pepsin Vial - H319, H315, H334	Pepsin Vial - P261, P264, P280, P337+P313, P304+P340, P342+P311	Pepsin Vial - Pepsin	None
10309756	RAPIDLab 348EX Wash	Electrode Conditioning Unit Dose Container - Exclaim 57mg Pepsin Vial - Health Hazard M348 Wash Solution - Exclaim	Electrode Conditioning Unit Dose Container - Warning 57mg Pepsin Vial - Danger M348 Wash Solution - Warning	Electrode Conditioning Unit Dose Container - H319, H315 57mg Pepsin Vial - H319, H315, H334 M348 Wash Solution - H317, H412	Electrode Conditioning Unit Dose Container - P264, P280, P337+P313 57mg Pepsin Vial - P261, P264, P280, P337+P313, P304 + P340, P342+P311 M348 Wash Solution - P280, P273, P302+P352, P333+P313, P362+P364, P501	Electrode Conditioning Unit Dose Container - Ammonium bifluoride 57mg Pepsin Vial - Pepsin M348 Wash Solution -reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1); 5-bromo-5-nitro-1,3-dioxane	None
10312556	Ready Sensor – pH	None	None	H412	P273, P501	Silver Nitrate	None
10311046	RAPIDLab 348EX pH Electrode Fill	None	None	H412	P273, P501	Silver Nitrate	None
10311047	RAPIDLab 348EX Na^+/K^+/Ca^{++}/ Cl^- Electrode Fill	None	None	H412	P273, P501	Silver Nitrate	None
10312557	Ready Sensor – Sodium (Na^+)	None	None	H412	P273, P501	Silver Nitrate	None
10330133	Ready Sensor – Chloride (Cl^-)	None	None	H412	P273, P501	Silver Nitrate	None
10315922	Ready Sensor – Calcium (Ca^{++})	None	None	H412	P273, P501	Silver Nitrate	None
10327404	Ready Sensor – Potassium (K^+)	None	None	H412	P273, P501	Silver Nitrate	None
10329872	RAPIDLab 348EX Wash (Japan)	Exclaim	Warning	H317, H412	P280, P273, P302+P352, P333+P313, P362+P364, P501	Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)	None

Hazard and Precaution Information

Danger

Warning

Warning!

H315 – Causes skin irritation.

H317 – May cause an allergic skin reaction.

H319 – Causes serious eye irritation.

H334 – May cause allergy or asthma symptoms or breathing difficulties if inhaled.

H412 – Harmful to aquatic life with long lasting effects.

P261 – Avoid breathing dust.

P264 – Wash hands thoroughly after handling.

P273 – Avoid release to the environment.

P280 – Wear protective gloves/protective clothing/eye protection/face protection.

P391 – Collect spillage.

P501 – Dispose of contents and container in accordance with all local, regional, and national regulations.

P302 + P352 – IF ON SKIN: Wash with plenty of soap and water.

P304 + P340 – IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.

P333 + P313 – If skin irritation or rash occurs: Get medical advice/attention.

P337 + P313 – If eye irritation persists get medical advice/attention.

P342 + P311 – If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.

P362 + P364 – Take off contaminated clothing and wash it before reuse.

P305 + P351 + P338 – IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Safety Data Sheets (MSDS/SDS) are available on siemens-healthineers.com/poc.

2 Introduction

The RAPIDLab 348EX system is a benchtop system that analyzes whole blood and dialysis fluids. It is intended for use by laboratory staff and clinicians processing a low to moderate volume of samples (20–30) each day.

Intended Use of the RAPIDLab 348EX System

The system is designed for the determination of pH, pCO_2, pO_2, Na^+, K^+, Ca^{++} or Cl^- and Hct in heparinized human whole blood samples. The minimum sample volume is 50 µL.

The results appear on the touch screen display in pH or nmol/l for H^+, mmHg or kPa for pCO_2 and pO_2, mmol/L for Na^+, K^+, Ca^{++} or Cl^-, and % for Hct.

The system also calculates the following parameters:

- Standard and actual bicarbonate ($HCO_3^-{}_{std}$ and $HCO_3^-{}_{act}$)
- Total carbon dioxide content ($ctCO_2$)
- Blood and extra-cellular fluid base excess (BE(B) and BE(ecf))
- Estimated oxygen saturation (O_2SAT)
- Estimated oxygen content (O_2CT)
- Arterial-alveolar oxygen tension difference (pO_2(A–a)) and arterial-alveolar oxygen tension ratio (pO_2(a/A))
- Anion gap (AnGap)
- Estimated total hemoglobin (ctHb(est))
- Calcium ion concentration adjusted to pH 7.4 (Ca^{++}(7.4))
- Arterial oxygen tension-inspired oxygen fraction ratio (pO_2/F_IO_2)

The system is also designed for routine determination of pH, pCO_2, Na^+, K^+, and Ca^{++} in acetate- and bicarbonate-based dialysis fluids. When used in dialysis fluid mode, the results are displayed on the touch screen in pH or H^+, mmHg or kPa for pCO_2, and mmol/L for Na^+, K^+, and Ca^{++}. In dialysis fluid mode, the system calculates the following parameters: actual bicarbonate ($HCO_3^-{}_{act}$) and total carbon dioxide content ($ctCO_2$).

Summary and Explanation

The RAPIDLab 348EX analyzer and reagents are semi-automated *in vitro* diagnostic (IVD) devices intended for professional use in Near Patient/ Point of Care or centralized laboratory locations. Information for quantitative measurement of each analyte measured on the RAPIDLab 348EX Blood Gas System are described below.

Measurements of blood gases **(pCO_2, pO_2)** and blood **pH** are used to aid in the diagnosis and treatment of acid-base disturbances.

Sodium, Potassium and Chloride measurements are used to aid in the diagnosis and treatment of electrolyte imbalances.

Ionized Calcium measurements are used to aid in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease, and tetany.

Hematocrit measurements are used to aid in the diagnosis of anemia and polycythemia.

The RAPIDLab 348EX Blood Gas System includes the following primary components:

Buffer Pack contains two buffers. The 7.382 buffer provides the calibration point for pH, electrolyte and hematocrit calibrations. The 6.838 buffer provides the slope point for 2-point pH and electrolyte calibrations.

Hct Slope reagent provides the slope point for 2-point Hct calibration.

Sensors available on the system are pH, Na^+, K^+, Ca^{++} or Cl^-, pCO_2, pO_2, reference, and Hct. pH, $Na^+/K^+/Ca^{++}/Cl^-$ and reference fill solutions are accessories that are required to support the electrochemical functioning of the respective sensors.

The **Reference electrode** acts as a reference in measuring and stabilizing the potential of the working electrode. Ref Refill and Reference Inner are replaceable accessories of the Reference sensor.

Wash reagent contains wash fluid which cleans the probe and sample path after analysis.

After sample analysis is complete, the waste bottle collects reagents, samples, and waste into the waste bottle.

Gas Cartridges are used for calibration. Gas 1 (cal) provides the calibration point for 1- and 2-point pCO_2 and pO_2 calibrations. Gas 2 (slope) provides the slope point for 2-point pCO_2 and pO_2 calibrations.

3 Handling Samples and Reagents

The requirements and procedures described here are based on techniques appropriate for pH, blood gas, dialysis fluid analysis, and electrolyte analysis.[1]

Collecting Blood Samples

Use proper medical supervision when selecting a site from which to collect blood samples, performing collection procedures, and documenting sample handling. Use sterile technique at all times to avoid infecting the puncture site.[1] The medical person responsible must approve the specific details of any collection.

BIOHAZARD

Handle all samples as if they contain pathogenic organisms. See *Chapter 4, Safety Information*, for recommended precautions when working with biohazardous materials.

Immediately expel any bubbles that occurred during the sample collection. Cap the sample device immediately after you collect the sample to avoid room air contamination. When you collect samples with a capillary tube, fill the capillary tube completely, cap it securely, and mix the sample thoroughly.

CAUTION

Never use mineral oil or mercury in syringes because these substances might alter sample values and damage the system.

Note To prevent hemolysis and maintain sample integrity, use capillary tubes that do not contain mixing beads.

For more information about collecting and handling patient samples, refer to Clinical and Laboratory Standards Institute. Blood Gas and pH analysis and Related Measurements: Approved Guideline—Second Edition; CLSI Document C46-A2; (Vol. 29, No. 8); 2009.

CAUTION

- Interpret results from patients anesthetized with halothane or nitrous oxide with care, as the pO_2 values may be unreliable due to the reduction of halothane or nitrous oxide by the pO_2 sensor.[2]
- Avoid using sample collection devices containing EDTA, citrate, oxalate and fluoride anticoagulants, as these anticoagulants have a significant effect on blood pH, Na^+, K^+, Ca^{++}, Cl^- and Hct.
- Avoid hemolyzed samples, as hemolysis causes elevated K^+ readings.
- Samples with elevated levels of salicylates, salicylate derivatives such as ibuprofen, and bromide (Br^-), can increase chloride readings, as can samples contaminated with perchlorate (ClO_4^-), thiocyanate (SCN^-), iodide (I^-) and nitrate (NO_3^-).
- Avoid using excessive levels of heparin anticoagulants, as they cause calcium-heparin chelation and decrease Ca^{++} levels.
- Interpret Hct results from patients on cardiopulmonary support or receiving autologous transfusion with care, as the Hct value can be lowered in these cases.
- Large changes in protein can affect reported Hct values by 1–1.35% per g/dL. High leukocyte counts in blood samples can also increase reported Hct values.

Sample Sources

The system can analyze samples obtained from the following sources:

Sample Source	Description
Arterial blood	Arterial blood is commonly recommended for use in blood gas studies because it accurately reflects acid-base physiology and oxygenation status of the patient. Arterial blood is routinely obtained from the radial, femoral, or brachial arteries. Other sites can be used following catheterization or surgical procedures.
Venous blood	Venous blood can provide satisfactory pH and pCO_2 values; however, venous pO_2 values may not be significant in routine clinical studies without simultaneous study of arterial pO_2. Venous samples are routinely obtained from an antecubital vein using vacuum tube collection systems. Other sites can be used as necessary. Reported venous oxygen saturation values must be labeled as such to ensure correct interpretation of the results.
Capillary blood	Capillary blood, when carefully collected under the proper conditions, resembles arterial blood and can be used for blood gas studies if the sample limitations are understood. Only small quantities of blood are required for capillary blood analysis. Capillary blood can be obtained from the heel, finger, or earlobe. The area chosen should be prewarmed or stimulated before the puncture to promote arterial circulation. The puncture should be deep enough to ensure that blood flow is free and rapid. Avoid hemolysing the sample, because potassium levels are falsely elevated in hemolyzed blood.

When correctly collected, arterial, venous, and capillary blood samples are also suitable for electrolyte determinations.

Sample Collection Devices

Note Collect dialysis fluid samples, either acetate or bicarbonate based, in sterile tubes or glass bottles.

Syringes

- Use Siemens heparinized syringes or use dry electrolyte-balanced lithium heparin as the preferred anticoagulant for analysis on Siemens blood gas analyzers when collecting blood samples.
- Ensure that the syringe is completely filled, as incomplete filling raises the level of heparin with respect to the sample.
- To minimize room air contamination, a concern in pO_2 determinations, avoid drawing air into the sample.
- Immediately after drawing the sample, expel all air from the syringe, cap it securely, and thoroughly mix the sample to minimize the possibility of clot formation.

Capillary Tubes

- Use Siemens capillary tubes or other capillaries may be used with the Siemens instruments, but they should be electrolyte-balanced lithium heparin capillaries to collect capillary blood.
- The nominal volume is 95 µL, but a minimum of 50 µL can be measured in micro sample mode.
- Ensure that the capillary tube is completely filled and the ends securely capped.
- Mix the sample thoroughly to minimize the possibility of clot formation.

CAUTION

Siemens does not recommend the use of mixing beads as they may cause hemolysis. If mixing beads are used, remove the mixing bead prior to sample introduction into the analyzer.

Vacuum Tube Collection Systems

Vacuum tube systems containing lithium heparin can be used for venous samples. Fill the tube completely and mix the samples by gentle inversion to minimize the possibility of clot formation.

Handling and Storing Samples

The following conditions can cause erroneous results even when samples are collected correctly:

- Metabolic activity in the sample that occurs between sampling and completion of analyses
- Contamination of the sample by room air

- Incorrect mixing of the sample before analysis

To minimize the errors these conditions can cause, use correct storage and handling techniques. You can minimize errors caused by metabolic changes by analyzing samples as soon as possible after collection. This is particularly important for pO_2, because the sample consumes oxygen during storage. The rate of oxygen consumption depends on several factors:

- Storage temperature
- White blood cell count
- Reticulocyte count

Observe the following sample-handling and storage steps when you obtain human whole blood samples:

- Analyze the sample as soon as possible to minimize oxygen consumption.
- Analyze blood collected for special studies, such as A-a O_2 gradients, or shunt studies, within 5 minutes of collection.
- Do not ice plastic syringes. Keep them at room temperature, so long as the blood is analyzed within 30 minutes of collection.
- Oxygen and carbon dioxide levels in blood kept at room temperature for 30 minutes or less are minimally affected, except in the presence of an elevated leukocyte or platelet count.
- For blood gas measurements, if you anticipate a prolonged time delay of more than 30 minutes before analysis, use glass syringes and store them in ice water.

  Note Do not use syringes stored in ice water for electrolyte determinations, as ice water effects on diffusion in and out of the red blood cells can cause unreliable potassium results. Storage in ice water applies only to blood gas measurements.

  You can store a sample collected in a glass syringe in the ice slurry for up to 2 hours without significant change in values for pH and pCO_2; however, this affects the K^+ values. Analyze samples with elevated white blood cell or reticulocyte counts immediately, because they deteriorate more rapidly.
- Before you analyze the sample, roll the syringe or the capillary tube between your palms and gently invert it several times to mix the sample thoroughly, until it is homogeneous.

  Blood cells settle during storage, and if you do not mix the sample well before analysis, the total hemoglobin results obtained can be falsely decreased or increased. Mix all samples using a consistent technique.

- If the sample is chilled or has been stored for more than 10 minutes, increase the mixing time to ensure that the sample is thoroughly mixed.
- Position any labels toward the back of the syringe barrel near the plunger so the label does not block your ability to insert the syringe into the system or cause it to fall off after it is inserted.
- Dispose of used sample devices according to your institution's infection control policy.

Note Clot formation can block sample pathways.

Dialysis Fluid Sample Handling

Observe the following practices when handling dialysis fluid samples:

- Store dialysis fluid samples at 2–8°C prior to analysis.
- Do not measure dialysis fluid samples if they are outside the range 6.5–8.0 pH, as this affects the performance of the Na^+ sensor.
- Measure dialysis fluid samples within 30 minutes of collection if pH and pCO_2 results are required.

CAUTION
Do not measure the acidic component of bicarbonate-based dialysis fluid.

Reagents

WARNING
Wear protective glasses, gloves, and coat when handling the reagents.

The reagents described in this section are for *in vitro* diagnostic use only. Siemens cannot guarantee the performance of the system in any of the following situations:

- Reagents other than those recommended are used.
- Expiry dates of reagents have been exceeded.
- Reagent change-by date has been exceeded.
- Reagents are not used or stored according to Siemens recommendations.
- Standard laboratory practices are not followed.
- The procedures in this manual are not followed.

Intended Use of Reagents

Reagent	Use
7.382 buffer	Provides the calibration point for pH, electrolyte and hematocrit calibrations. The 7.382 buffer is buffered to a pH of 7.382 at 37°C and is NIST traceable.
6.838 buffer	Provides the slope point for 2-point pH and electrolyte calibrations. The 6.838 buffer is buffered to a pH of 6.838 at 37°C and is NIST traceable.
Wash	Washes the probe and sample path.
Deproteinizer	Removes protein buildup from the sample path. Deproteinizing is part of regular preventive maintenance for the system.
Conditioner	Cleans and conditions the pH and sodium sensors. Conditioning is part of regular preventive maintenance for the system.
Hct slope	Provides the slope point for 2-point Hct calibrations. Hct slope solution uses NIST traceable salts.

Composition of the reagents and the concentration of the active ingredients

RAPIDLab 348EX 6.8/ 7.3 Buffer - 10309757

Calibrant solution	Chemical
0.47%	Sodium Chloride
0.03%	Potassium Chloride
0.02%	Calcium Acetate
0.06%	Lithium Chloride
0.24%	Sodium Hydroxide
1.68%	MOPS (3-morpholinopropane-1-sulfonic acid)
0.05%	surfactant
0.34%	total Biocide
0.00003%	dye
98.7%	di water

Slope solution	Chemical
0.36%	Sodium Chloride
0.06%	Potassium Chloride
0.05%	Calcium Acetate
0.03%	Lithium Chloride
0.35%	Sodium Hydroxide
0.18%	MOPS (3-morpholinopropane-1-sulfonic acid)
2.09%	surfactant
0.05%	total Biocide
0.37%	dye
0.00003%	di water
97.4%	Deionised Water

RAPIDLab 348EX Wash - 10309756

Wash solution	Chemical
0.56%	Sodium Chloride
0.03%	Potassium Chloride
0.02%	Calcium Acetate
0.36%	Sodium Acetate
0.12%	Lithium Acetate Dihydrate
0.05%	surfactant
0.30%	total Biocide
0.00005%	dye
99.4%	Deionised Water

Conditioner Kit - 10311078

Conditioner udc[a]	Chemical
0.82%	Sodium Chloride
0.57%	Ammonium Hydrogen Difluoride
99.5%	Deionised Water

a. UDC = unit dose container

Deproteinizer Kit - 10309775

Deproteinizer udc[a]	Chemical
0.818%	Sodium Chloride
0.030%	Potassium Chloride
0.018%	Calcium Acetate
0.004%	Lithium Chloride
0.003%	15% Hydrochloric Acid
0.200%	Biocide
98.200%	Deionised water

a. UDC = Unit Dose Container

pepsin vial	Chemical
100.0%	Pepsin

Hct Slope - 10309776

Hct Slope ampoule	Chemical
0.164%	Sodium Chloride
0.030%	Potassium Chloride
0.018%	Calcium Chloride
0.209%	MOPS (3-morpholinopropane-1-sulfonic acid)
0.200%	Biocide
99.900%	Deionised water

RAPIDLab Reference Electrode Fill - 10311081

4M KCl ref fill udc[a]	Chemical
29.82%	Potassium Chloride
91.0%	Deionised Water

a. UDC = Unit Dose Container

RAPIDLab 348EX $Na^+/K^+/Ca^{++}/Cl^-$ Electrode Fill - 10311047

NaKCaCl Electrode fill udc[a]	Chemical
0.818%	Sodium Chloride
0.030%	Potassium Chloride
0.018%	Calcium Chloride

NaKCaCl Electrode fill udc[a]	Chemical
0.050%	Biocide
0.003%	Silver Nitrate
1%	Brij 700
99.800%	Deionised Water

a. UDC = Unit Dose Container

RAPIDLab 348EX pH Electrode Fill - 10311046

pH Electrode fill udc[a]	Chemical
1.753%	Sodium Chloride
0.738%	Disodium Hydrogen Orthophosphate
0.680%	Potassium Dihydrogen Orthophosphate
0.050%	Biocide
0.003%	Silver Nitrate
1%	Brij 700
99.500%	Deionised Water

a. UDC = Unit Dose Container

Final concentration of preservatives and toxic substances in the individual components/products

Sl. No	Components Name	Preservative / Toxic Substance	Concentration
1	RL348EX Starter Kit + Ca ROW	Glokill 77	2000ppm
		Proclin 300	800ppm
		Bronidox L	500ppm
		Glydant	2910ppm
2	RL348EX Starter Kit + Cl ROW	Glokill 77	2000ppm
		Proclin 300	800ppm
		Bronidox L	500ppm
		Glydant	2910ppm
3	RL348EX Starter Kit BG ROW	Glokill 77	2000ppm
		Proclin 300	800ppm
		Bronidox L	500ppm
		Glydant	2910ppm

4	RAPIDLab 348EX $Na^+/K^+/Ca^{++}/Cl^-$ Electrode Fill	Bronidox L	500ppm
		Silver Nitrate	0.003 w/w%
5	RAPIDLab 348EX pH Electrode Fill	Bronidox L	500ppm
		Silver Nitrate	0.003 w/w%
6	Ready Sensor – Chloride (Cl^-)	Bronidox L	500ppm
		Silver Nitrate	0.003 w/w%
7	Ready Sensor – Sodium (Na^+)	Bronidox L	500ppm
		Silver Nitrate	0.003 w/w%
8	Ready Sensor – pH	Bronidox L	500ppm
		Silver Nitrate	0.003 w/w%
9	Hct Slope	Glokill 77	2000ppm
10	RAPIDLab 348EX Wash	Glokill 77	2000ppm
		Proclin 300	1500ppm
		Bronidox L	2000ppm
11	RAPIDLab 348EX 6.8/7.3 Buffer	Proclin 300	800ppm
		Glydant	2910ppm
12	Deproteinizer	Glokill 77	2000ppm
13	Ready Sensor – Calcium (Ca^{++})	Tetrahydrofuran*	Traces
		Bronidox L	500ppm
		Silver Nitrate	0.003 w/w%
14	Ready Sensor – Potassium (K^+)	Tetrahydrofuran*	Traces
		Bronidox L	500ppm
		Silver Nitrate	0.003 w/w%

*THF is used as solvent bond in the 348EX probe slide (part of instrument), and a carrier solvent during manufacture of Calcium and Potassium ion-selective membranes for use in RL348EX electrodes. In the Potassium and Calcium sensors only a trace of Tetrahydrofuran is present as it is the solvent in the membrane which evaporates during the manufacturing process.

Storage

- Store all reagents & consumables listed in page 2 (except RAPIDLab Reference Electrode Fill & Gas Cartridge Pack) away from direct sunlight at 4–25°C.
- Store Gas Cartridge Pack away from direct sunlight at 18–25°C.
- Store RAPIDLab Reference Electrode Fill away from direct sunlight at 10–25°C.
- Discard 7.382 and 6.838 buffers 21 days after opening.
- Do not use reagents after the expiry date.

- Discard Deproteinizer, Conditioner, Hct Slope and electrode fill solutions after a single use.

Shelf Life

RAPIDLab 348EX Component Shelf Life Guidelines:

RAPIDLab Component:	Shelf Life in Months	Temperature range	Acceptable light conditions for storage
RAPIDLab Deproteinizer Solution UDC[a]	24	4°C–25°C	away from light
Conditioner Solution UDC[a]	24	4°C–25°C	away from light
Hct Slope	18	4°C–25°C	away from light
RAPIDLab 348EX 6.8/7.3 Buffer	12	4°C–25°C	away from light
RAPIDLab 348EX Wash	18	4°C–25°C	away from light

a. UDC = unit dose container

Shelf Life & Typical Use Life of Sensors

Sensor	SMN	Shelf-Life	Use-Life
Ready Sensor - pH	10312556	24 months	180 days
Ready Sensor - pCO_2	10317498	24 months	180 days
Ready Sensor - pO_2	10324408	24 months	180 days
Ready Sensor - Sodium (Na^+)	10312557	24 months	180 days
Ready Sensor - Potassium (K^+)	10327404	24 months	180 days
Ready Sensor - Calcium (Ca^{++})	10315922	24 months	90 days
Ready Sensor - Chloride (Cl^-)	10330133	24 months	180 days
Ready Sensor - Reference (Ref)	10323084	24 months	180 days
Ready Sensor - Reference Inner	10329947	24 months	180 days
Ready Sensor - Ref Refill	10230458	24 months	180 days
Ready Sensor - Hct	10309783	24 months	180 days

Handling and Preparation

The following reagents require no preparation before use:

- 7.382 buffer
- 6.838 buffer
- Hct slope
- Wash
- Conditioner

Prepare Deproteinizer as directed by the instructions on the package.

4 System Operation

Materials Provided

Materials Provided		Special Materials Required (Not Provided)
		RAPIDLab 348EX System
Product Name	**REF**	**10844678**
Ready Sensor - Sodium (Na^+)	10312557	X
Ready Sensor - pH	10312556	X
Ready Sensor - pO_2	10324408	X
Ready Sensor - Hct	10309783	X
Ready Sensor - pCO_2	10317498	X
Ready Sensor - Calcium (Ca^{++})	10315922	X
Ready Sensor - Potassium (K^+)	10327404	X
Ready Sensor - Reference (Ref)	10323084	X
Ready Sensor - Chloride (Cl^-)	10330133	X
Hct Slope	10309776	X
Ready Sensor - Ref Refill	10320458	X
RAPIDLab 348EX 6.8/7.3 Buffer	10309757	X
Gas Cartridge Pack	10309768	X

Materials Provided		Special Materials Required (Not Provided)
		RAPIDLab 348EX System
Product Name	**REF**	**10844678**
RL348EX Starter Kit + Ca ROW	10844682	X#
RL348EX Starter Kit + Cl ROW	10844683	X#
RL348EX Starter Kit BG ROW	10844684	X#
RAPIDLab Reference Electrode Fill	10311081	X
RAPIDLab 348EX pH Electrode Fill	10311046	X
RAPIDLab 348EX $Na^+/K^+/Ca^{++}/Cl^-$ Electrode Fill	10311047	X
Ready Sensor - Reference Inner	10329947	X
RAPIDLab 348EX 6.8/7.3 Buffer (Japan)	10336723	X
Deproteinizer	10309775	X
Conditioner Kit	10311078	X
MULTICAP capillary tubes, 50 x 100 µl	10323539	Optional
MULTICAP capillary tubes, 500 x 100 µl	10322912	Optional
Caps for 140 µl capillary tubes, pack of 100	10311054	Optional
Blood Collection Capillaries Multicap	10311005	Optional
MULTICAP capillary tubes, 50 x 140 µl	10314796	Optional
Plastic capillary tube, 500 x 140 µl	10313226	Optional
Plastic capillary tube, 50 x 100 µl	10313252	Optional
Plastic capillary tube, 500 x100 µl	10322986	Optional
Plastic capillary tube, 500 x 175 µl	10316361	Optional
Plastic capillary tube, 50 x 140 µl	10320937	Optional
Plastic capillary tube, 50 x 175 µl	10324363	Optional
Capillary Caps	10328655	Optional
Blood Collection Capillaries Multicap 50 x 175µl Pack	10325868	Optional
Blood Collection Capillaries Multicap	10315378	Optional
Test/Blank sensor $K^+/Ca^{++}/Cl^-$ (TB3)	10311665	Optional
Test/Blank sensor ref (TB5)	10327492	Optional
RAPIDLab 348EX Wash	10309756	X

Materials Provided		Special Materials Required (Not Provided)
		RAPIDLab 348EX System
Product Name	**REF**	**10844678**
MULTICAP blood collection kit, containing 100 x 60 µl capillary tubes and 200 caps	10314213	Optional
Adaptors for capillaries, pack of 100	10330785	X
Capillary Caps	10311053	Optional
Blood Collection Capillaries for pH/ Blood Gas	10310990	Optional
Blood Collection Capillary Tubes 100µl	10321712	Optional
Blood Collection Capillary Tubes 140µl	10327012	Optional
Blood Collection Capillary Tubes 140µl	10327283	Optional
Calibration Verification Material (CVM)	10316535	Optional
RAPIDQC Hct Level A	10311392	X
RAPIDQC Hct Level B	10311393	X
RAPIDQC Complete Level 1	10309925	X
RAPIDQC Complete Level 2	10309926	X
RAPIDQC Complete Level 3	10309927	X
Pre-heater tube kit	10309777	Maintenance spare
Power supply cord, with connector	*	X
Probe and tubing kit	10309797	Maintenance spare
Probe and housing kit	10311628	Maintenance spare
Probe protectors	10324749	X
Bottle tubing kit	10309778	Maintenance spare
Sample pump tubing kit	10309780	Maintenance spare
Reagent pump tubing kit	10309781	Maintenance spare
Sample and reagent pump tubing kit	10309779	Maintenance spare
Clot removal line, 0.5m (191/2inches)	10311063	X

Materials Provided		Special Materials Required (Not Provided)
		RAPIDLab 348EX System
Product Name	**REF**	**10844678**
Drip tray	10311630	Maintenance spare
Gas cartridge venting tool	10314899	X
Gas cartridge removal tool	10329532	X
Caps for 140 µl capillary tubes, pack of 100	10311054	Optional
Wash Pack (Japan only)	10329872	X

*Depends on Country
#Only with new Instrument

Powering Up the RAPIDLab 348EX System

Perform these steps if the system is not already turned on.

1. Connect the power cord to an appropriate power outlet.
2. Press the Power switch to turn on the system.

   The system begins the power-up sequence and displays Not Ready until it is ready to function.

   The system performs a number of internal tests, then displays a Warming Up message.

   Note Pressing the touch screen for 5 seconds while the first Warming Up screen displays causes the screen calibration feature to appear. This lets you recover the screen if it requires calibration before use. See *Calibrating the Touch Screen,* page 68.

What You Can Do during Warmup

While the system is warming up, you can perform the following steps.

1. Prime the system to remove bubbles from the calibrant lines by selecting **Settings > Maintenance** > **Prime**.

   If necessary, repeat the routine to thoroughly prime the system.
2. Condition the sensors by selecting **Settings > Maintenance** > **Condition**.
3. Initiate a 2-point calibration by selecting **Settings > Maintenance** > **Calibration > Full 2 Point**.

   The data from this calibration is not used.

When the System Reaches Operating Temperature

When the system reaches operating temperature, it automatically carries out 2 full 2-point calibrations, 10 minutes apart.

1. Wait for the calibrations to complete
2. When the system displays the Ready screen, select **Ready > QC**.
3. Perform the appropriate quality control procedures.

   See *Section 9, Quality Control*.

Selecting Options and Entering Data

Tap the screen lightly in a selection area or button to select an option or to navigate in a list of items:

- To choose an option from a list, select the corresponding button on the screen.
- To enter data, use the onscreen keypad or the barcode reader.
- Select **Enter** to save that data.
- To return to the Ready screen, select **Back** to step back through the screens.
- To delete the last character in the currently highlighted line, select **C** on the onscreen numeric keypad.

CAUTION

Do not use a stylus or other hard object to select items on the touch screen. Doing so might damage the screen.

Entering Your Operator ID and Password

Entering Your Operator ID

If you configure the system to require an Operator ID, the system prompts you to enter your operator ID when you lift the probe and does not allow sample or QC analysis to continue until you have entered your ID. See *Section 13,* , for details on configuring this requirement.

1. Enter from 1–16 digits for an operator ID.

   Use the hyphen to insert dashes.

2. To continue with sample analysis, select **Enter**.

You can also use the barcode reader to enter the operator ID.

Your operator ID is printed on the sample or QC report.

Entering Your Password

Depending on the security options selected in Setup, the system might prompt you to enter your password before performing some tasks. If prompted for your password, perform the following steps:

1. At the prompt, enter your password.

   If you have an alphanumeric password, use the barcode scanner.

2. Select **Enter**.

Menu Map

The touch screen displays a series of menus and display screens that let you navigate through the system functions, select and perform specific actions, and display results. See *Appendix 14, Menu Map* for a list of the principal menus. Each of these menus leads to a series of submenus relevant to your selections.

Analyzing Syringe Samples

BIOHAZARD

Wear personal protective equipment. Use universal precautions. See *Section 4, Safety Information*, for recommended precautions when working with biohazardous materials.

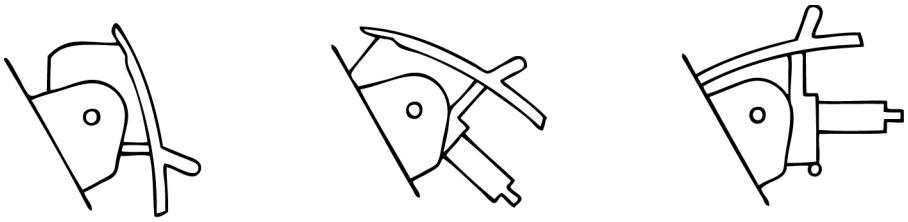
1. Observe all rules and guidelines in *Collecting Blood Samples*, page 31.

   Note If you have a priority sample, but a message is displayed indicating that the system is busy, select **Cancel** to interrupt the system. If Cancel is not available, wait until the message is not displayed to analyze the patient sample.

2. Select **Ready > Syringe**.

3. Lift the probe lever to the second position (labeled 3, in Figure 1.)

Figure 1: Probe Lever Positions



1 2 3

1. Closed position
2. Sampling position for ampules and other open-top containers
3. Sampling position for syringes and capillaries

Note If you have pushed the probe cover up to the first position, which is normally used for sampling from ampules and open-top containers, the system displays a message asking you to confirm the sample type.

4. If required, enter your Operator ID (1–16 digits).
5. Wait for the screen to direct you to present the sample.

   To cancel this operation, simply close the probe.
6. Slide the syringe sample onto the probe and gently push the probe sleeve back.
7. Wait for the system to beep, indicating that the probe sleeve is in the correct position, then select **Measure**.

   Try to position the probe to obtain the most representative sample.
8. Hold the sample in place until the system beeps a second time, and a Sample Complete message displays.

9. Remove the syringe and close the probe.

   The system processes the sample, displays a Moving Sample - Please wait message, then displays test results on 1 or 2 Measuring screens. All measured analytes are displayed. Any sensors unavailable for testing appear without numeric values.

CAUTION

Do not leave the sample device in the sample port after the system prompts you to remove it. The system performs a wash after each sample analysis. Leaving the sample device in place while the system performs a wash could contaminate that wash with blood and adversely affect the next sample or system operation.

10. View the results.

Entering Patient Data

1. To enter patient data, on the Measuring screen (which you can reach in a variety of ways), select **Enter Patient Data**.

   Note The Enter Patient Data screen times out and returns to the Measuring screen after 45 seconds of inactivity.

2. Navigate to the field you want to change.
3. Using the onscreen keypad or the barcode reader, enter the data in the highlighted field:
   - Operator ID and Patient ID: 1–16 digits. Use the hyphen key to insert dashes.
   - Patient temperature: 10.0–43.9°C
   - *c*tHb: 2.0–25.0 g/dL (20–250 g/L or 1.2–15.5 mmol/L)
   - F_IO_2: 15.0–100.0%

   The system uses the values entered for patient temperature, *c*tHb, and F_IO_2 when calculating the results.
4. Select Enter to save the data.

   Note If you do not enter patient data, the system uses normal (default) temperature (37°C) and F_IO_2 (20.9%) values in the calculations. If Hct was measured, the calculated *c*tHb value is used; otherwise, the system uses 15 g/dL (150 g/L, 9.3 mmol/L). However, the system reports:
   - O_2CT only if *c*tHb is entered or *c*tHb(est) is available.
   - pO_2(A-a), pO_2(a/A), and pO_2/F_IO_2 only if F_IO_2 is entered.

You can correct results for patient temperature, *c*tHb, and F_IO_2 after measurement. See *Recalling Sample Data,* page 60.

Depending on the number of parameters you selected to be measured, the results are on 1 or 2 screens. Measurement is complete when the equals sign on the display stops flashing.

The screen displays all measured parameters and up to 8 calculated parameters. If you select more than 8 calculated parameters, only the first 8 appear on the screen, but all selected parameters are printed and, if an LIS connection is configured, sent to the LIS.

While displaying and printing the results, the system washes the probe and sample path. When the wash has finished, the measurement block light goes off.

The system automatically returns to the Ready screen if it is inactive for 30 seconds.

Analyzing Capillary Samples

BIOHAZARD
Use universal precautions. See *Section 4, Safety Information*, for recommended precautions when working with biohazardous materials.

1. Select **Ready > Capillary**.
2. Lift the probe lever to the second position.

   This is the same position as for syringe samples.
3. If required, enter from 1–16 digits for your Operator ID.
4. The measurement block light comes on and the Probe Open screen displays.
5. Remove the caps from the end of the capillary and carefully fit a capillary adaptor.
6. Slide the adapter onto the probe, then select **Measure**.

   The system beeps and, when sampling is complete, displays the Sampling screen.

   Note If you have pushed the probe cover up to the first position, which is normally used for sampling from ampules and open-top containers, the system displays a message asking you to confirm the sample type.

7. Hold the capillary in place.

   The system beeps and, when sampling is complete, displays the Sampling complete screen.

8. Remove the capillary and adapter and close the probe.

   The Moving sample screen displays while the sample is moving, then the Measuring screen displays.

   If a bubble or short sample is detected, the system alerts you to this condition. See *Measuring a Short Sample or a Sample with a Bubble*, page 58, for details.

   The Measuring screen dynamically updates the numeric data as the test proceeds. Any sensors unavailable for testing appear without numeric values. The equals sign flashes until the result for that parameter is complete.

9. To enter patient data, select **Enter Patient Data** on the Measuring screen.

   The Enter Patient Data screen appears, along with the onscreen keypad.

   Note The Enter Patient Data screen times out and returns to the Measuring screen after 45 seconds of inactivity.

10. On the Enter Patient Data screen, enter the data in the highlighted fields:

    - Operator ID and Patient ID: 1–16 digits. Use the hyphen key to insert dashes.
    - Patient temperature: 10.0–43.9°C
    - *c*tHb: 2.0–25.0 g/dL (20–250 g/L or 1.2–15.5 mmol/L)
    - F_IO_2: 15.0–100.0%.

    Note *c*tHb and F_IO_2 do not apply in dialysis fluid analysis.

    The system uses the values entered for patient temperature, *c*tHb, and F_IO_2 when calculating the results.

Note If you do not enter patient data, the system uses normal (default) temperature (37°C) and F_IO_2 (20.9%) values in the calculations. If Hct was measured, the calculated *c*tHb value is used; otherwise, the system uses 15 g/dL (150 g/L, 9.3 mmol/L). However, the system reports:

- O_2CT only if *c*tHb is entered or *c*tHb(est) is available, and
- pO_2(A-a), pO_2(a/A), and pO_2/F_IO_2 only if F_IO_2 is entered.

You can correct results for patient temperature, *c*tHb, and F_IO_2 after measurement. See *Recalling Sample Data,* page 60.

11. Select **Enter** when you are done.
    - If the system is still measuring, the Measuring screen appears.
    - If measuring is completed, the Results screen appears.

    Note If the system is inactive for about 30 seconds, it returns to the Ready screen.

12. To see the calculated parameters, select the down arrow to display the second Results screen.

    Up to 8 parameters appear on this screen, but all the selected parameters are printed.

Interpreting Results, Syringe and Capillary Samples

If the measured values are outside the reference ranges, an arrow indicates whether they are above or below the range. Results display on two consecutive screens. Calculated parameters, if selected, appear on the second Results screen. See *Section 13,* , for details on reference ranges and calculated parameters. To see this second screen, select the down arrow.

Note Hct determinations depend on electrolyte concentrations (that is, conductivity). The system corrects for high/low levels of the electrolytes Na^+ and K^+ that would alter conductivity, and hence affect Hct measurement. The system flags the Hct value with u (uncorrected) during measurement. The Hct value is updated when the electrolyte values are known.

If the Na^+ value is not available at measurement endpoint, the Hct result is flagged as uncorrected on the display and on the printout.

While displaying and printing the results, the system washes the probe and sample path. When the wash has finished, the measurement block light goes off.

Analyzing Dialysis Fluid Samples

1. On the Ready screen, select **Dialysis Fluid (DF)**.
2. Lift the probe to the first position.
3. If required, enter from 1–16 digits for your Operator ID.
4. The Probe Open screen displays and the measurement block light comes on.

   The screen displays the instruction Present Sample.
5. Using the edge of the sample container, gently push the probe sleeve back, immersing the probe in the sample.

   The system beeps and starts sampling when the probe sleeve is in the correct position.

CAUTION
Do not allow the probe tip to touch the bottom of the sample container.

6. Hold the sample in place.

   The system displays a Sampling message, then beeps when sampling is complete.
7. Remove the sample and close the probe.

   The Moving sample screen displays while the sample is moving, then the Measuring screen displays.

   If it detects a bubble or short sample, the system alerts you to this condition. See *Measuring a Short Sample or a Sample with a Bubble,* page 58.

   The Measuring screen dynamically updates the numeric data as the test proceeds. Any sensors unavailable for testing appear without numeric values. The equals sign flashes until the result for that electrolyte is complete.
8. To enter patient data, select **Enter Patient Data** on the Measuring screen.
9. On the Enter Patient Data screen, enter the data in the highlighted fields:
   - **Operator ID** and **Patient ID**: 1–16 digits. Use the hyphen key to insert dashes.
   - **Patient temperature**: 10.0–43.9°C

   After 45 seconds of inactivity, the Enter Patient Data screen times out and returns to the Measuring screen.

Note If you do not enter patient data, the system uses normal (default) temperature (37°C) value in the calculations.

If necessary, you can correct results for patient temperature after measurement. See *Recalling Sample Data,* page 60.

10. When you are done, select **Enter** to save the results.
11. One of the following screens appears:
    - If the system is still measuring, the Measuring screen appears.
    - If measuring is completed, the Results screen appears.

    Note If the system is inactive for about 30 seconds, it returns to the Ready screen.
12. To see the calculated parameters, select the down arrow to display the second Results screen.

    Up to 8 parameters appear on this screen, but all the selected parameters are printed. Calculated parameters do not apply for dialysis fluid analysis.

Measuring a Micro Sample

If the system detects a sample that is less than 95 µL, it first determines whether it has sufficient sample (minimum 50 µL) to perform the test in micro sample mode.

If the system could not gather sufficient sample material, the message Bubble in Sample or Short Sample displays. See *Measuring a Short Sample or a Sample with a Bubble,* page 58 for details.

If the system detects enough sample material for a micro sample, it displays the Micro Sample screen with the message Micro Sample in Progress for about 8 seconds.

To cancel the test, select **Cancel** during this interval. The system then enters the wash cycle to flush the sample out of the measurement block. When the wash cycle completes, the display returns to the Ready screen.

If you do not select **Cancel**, the system positions the sample under the first three sensors and measures it. The Measuring screen displays, and the system automatically measures the sample in micro sample mode.

After the first three sensors process the sample, the system displays Please wait, and the sample then moves on to the remaining sensors and is measured.

When the measurement is complete the system displays the results as usual, and the printout shows Micro Sample.

If the system cannot position the sample for the second part of the measurement, the sample is flushed out of the measurement block and the display returns to the Ready screen. The successfully measured parameters are reported.

Note If you select **Enter Patient Data** to enter patient data when the Cancel message is displayed, you can no longer cancel the measurement.

Measuring a Short Sample or a Sample with a Bubble

If the system detects a short sample or a bubbles in a sample, it offers you the following choices:

- Manually reposition the sample so no air bubbles are under the sensors, then continue with the analysis.
- Flush the sample out of the measurement block and repeat the analysis.

The system beeps and displays either the Short sample screen or the Bubble in sample screen, as appropriate.

This message displays for 1 minute. If you take no action, the system flushes the sample out of the measurement block.

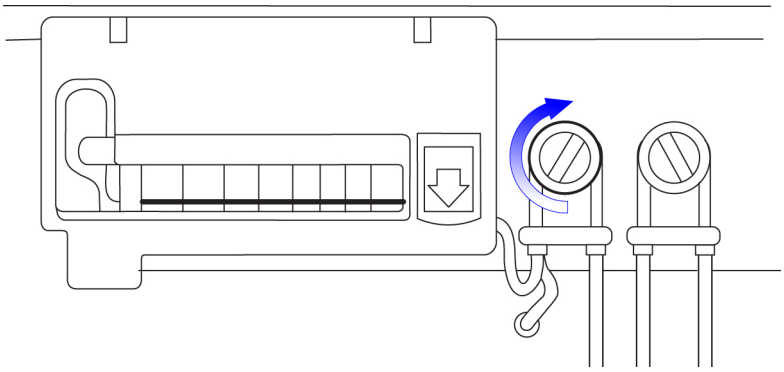
Continuing with the Short or Bubble Sample Analysis

When the Short Sample or Bubble in Sample screen displays the message Reposition the sample and select **Measure** to measure, perform the following steps:

1. To measure the sample, lift the front cover and look at the measurement block.

2. Turn the sample pump rotor (the sample pump is the left pump) in the direction indicated (Figure 2), so that the sample is repositioned directly beneath the sensors for which results are required.

Figure 2: Repositioning the Samples



CAUTION
Do not move sample pump rotor counterclockwise, as KCl from the reference sensor might contaminate the sample.

CAUTION Ensure that the sample is repositioned directly beneath the sensors for which results are required. For example, for pO_2 and pCO_2 results, the sample must be positioned under the pO_2 and pCO_2 sensor with no air bubbles present. For electrolyte results, the sample must be positioned under the electrolyte and reference sensors with no air bubbles present. Air bubbles present under one of the sensors as a result of incorrect sample repositioning may lead to erroneous results.

3. When you are satisfied that the sample is correctly repositioned select **Measure**.

   The sample analysis continues. No further Short sample or Bubble in sample messages display, although the sample is flagged on the printout.

   Note The system beeps twice, every 3 seconds, until you take some action.

Cancelling the Sample Analysis

Select **Cancel** to end the sample analysis before it finishes.

The system flushes the sample out of the measurement block and the display returns to the Ready screen.

Recalling Sample Data

The system retains the data for the last 250 samples measured. The Data Recall menu lets you perform the following functions:

- Recall data for each sample.
- Enter or change patient data for each sample.
- Print results for each sample.

1. Select **Ready > Settings > Data Recall > Sample Data**.
2. Select one of the user actions or **Back**, or scroll through the list of results.

   In the initial display, the first result is highlighted on the screen.
3. Select an item that you want to print or for which you want to view all the results.
4. Select **Back** to return to the Data Recall screen.

Viewing Recalled Sample Data

The results list shows the data stored in the system's memory for the last sample measured. It includes the Sample identification data: analysis time and date, sample number, patient ID, and operator ID (if entered).

1. To view the recalled data, select the result that you want to view by performing one of the following actions:
   - Use the scroll bar on the results list to locate a particular result.
   - Select the up and down arrows at the top and bottom of the scroll bar to move the results up or down.
2. Highlight a particular result in the list by selecting it.
3. Select **View Result** to display the full set of results for the highlighted item.

   Note The system reports O_2CT only when *c*tHb was entered or *c*tHb(est) is available, reports and pO_2(A-a), pO_2(a/A), and pO_2/F_IO_2 only when F_IO_2 was entered.

   The results appear on 1 or 2 screens, depending on the number of parameters included for that sample. The first results screen shows up to 8 numeric values.

4. To navigate between the first and second screens, select the up or down arrows.

   If no screen 2 parameters exist for this sample, pressing the down arrow on the first results screen displays the message No parameters selected.

5. Select **Back** to return to the Sample Data screen or select the up arrow to return to the first results screen.

Entering Patient Data for a Recalled Sample

1. To enter or change the patient data for the highlighted result, select **Enter Patient Data** on the Data Recall .... Sample Data screen.

   Note The Enter Patient Data screen times out and returns to the Measuring screen after 45 seconds of inactivity.

2. Select a field for which you want to enter or change the data.

   The data entry area for the selected field is highlighted. No fields are selected by default.

3. Enter the data in the highlighted fields on the Enter Patient Data screen.

   On the onscreen keypad, select **C** to delete the last character in the currently highlighted line. Use the up and down arrow keys to navigate between screens.

   You can correct results for patient temperature, *c*tHb, and F_IO_2 after measurement, within the following ranges:

   - Operator ID and Patient ID: 1–16 digits. Use the hyphen key to insert dashes.
   - Patient temperature: 10.0–43.9°C
   - *c*tHb: 2.0–25.0 g/dL (20–250 g/L or 1.2–15.5 mmol/L)
   - F_IO_2: 15.0–100.0%

   Note If you attempt to enter data outside the reasonable ranges, the system rejects the entered value. Selecting another data entry line or selecting **Enter** causes the system to beep 3 times and either blank the field with the unacceptable data or revert to the previous reasonable data.

   If you do not enter patient data, the system retains the values from the recalled record.

4. When you are done, select **Enter** to save the results.

Note If the system is inactive for about 30 seconds, it returns to the Data Recall screen without saving your entries.

Printing Recalled Results

To print the highlighted result, on the Data Recall .... Sample Data screen, select **Print Result**.

The Print Result screen displays, with a **Please wait** message.

If a printer error occurs, such as the printer being out of paper, an error message screen appears briefly before the Print Result screen.

The printout shows the date and time the sample was analyzed, not the time of recall.

Note The system prints only 1 copy, regardless of copy number selected in **Printer Options**.

After printing the results, the system returns to the Data Recall .... Sample Data screen.

Standby Mode

Standby mode conserves reagents. The sensors are kept wet and the pump tubes are moved from time to time to keep them in good condition. The system does not calibrate while in standby mode, but it automatically calibrates as required when restarted, before allowing sample measurements.

Entering Standby Mode

1. Select **Ready > Settings > Standby**.

Restarting from Standby Mode

1. To immediately restart the system, on the Standby screen, select **Restart**.

   The system returns to the Main Menu screen.

2. To set a time when the system automatically restarts, select **Set auto restart time**.

   The system displays the Set auto restart time screen.

3. In the Auto restart at field, specify a restart time in 24-hour, hh:mm format.

   The system checks your entry for validity and automatically restarts at that time.

5 Calibrating Your System

Selecting Calibration Method and Entering Gas Values

1. Select **Ready > Settings > Operating Setup > Calibration.**
2. Select **Timing** or **Gas Values** and proceed to the next sections to set up the calibration, as follows:

Note The system calibrates automatically, as necessary, based on the methods and timing mode that you configure.

Choosing the Calibration Timing Mode

Select fixed or flexible calibration timing, as described in the following table:

	Fixed Time	**Flexible Time**
Interval between calibrations	30 or 60 minutes	Maximum interval: 30 or 60 minutes
Description	The system calibrates automatically at the interval you specify: 30 or 60 minutes.	The system calibrates automatically as required and calculates the time between calibrations to optimize performance.

	Fixed Time	Flexible Time
Result	• A 1-point calibration is carried out at every interval. • A full 2-point calibration (not Hct) is carried out at every fourth interval. • Hct slope check is prompted at least every 25 days.	• The time between 1-point calibrations is between 10 minutes and the maximum time interval selected. • A full 2-point calibration (not Hct) is carried out at every fourth interval. • Hct slope check is prompted at least every 25 days.
Example	If interval = 30 minutes, the system automatically carries out a 1-point calibration every 30 minutes, and a 2-point calibration every 2 hours.	If interval = 60 minutes, the system automatically carries out a 1-point calibration at least once every 60 minutes and a 2-point calibration at least every 4 hours.

Automatic Calibrations, Independent of Timing Mode

In both fixed and flexible time methods, the system automatically calibrates after certain maintenance routines; for example, the Disinfect, Deproteinize, and Condition routines. It also calibrates if the measurement block door has been opened and closed or if a sampling fault occurs; for example, Sample not detected.

Selecting Calibration Timing

1. Select **Calibration > Timing**.
2. On the Timing screen, select the calibration timing method, **Fixed** or **Flexible** (default).

   For an explanation of fixed and flexible time modes, see *Calibration Overview,* page 177.
3. On the same screen, select the calibration interval, **30 minutes** (default, recommended) or **60 minutes**.
4. Select **Back** to return to the Calibration screen.

Calibrating Gas Values for the pCO_2 and pO_2 Sensors

Gas 1 provides the calibration point for 1- and 2-point pCO_2 and pO_2 calibrations. Gas 2 provides the slope point for 2-point pCO_2 and pO_2 calibrations.

CAUTION
When handling compressed gas cylinders, be sure to observe the safety precautions described in *Handling Compressed Gas Cartridges*, page 24.

1. Select **Calibration > Gas Values**.
2. Select the field for which you want to enter a gas value.

CAUTION
Do not change the default settings for gas values when using the Siemens gas pack.

3. Enter the appropriate value into the highlighted field.

   The maximum ranges available for gas values are:

	Cal	Slope
CO_2	4.00–6.00%	8.00–12.00%
O_2	10.00–14.00%	0.00–2.00%

Default settings:

Method:		
time	flexible	
interval	30 minutes	
Gas values:		
cal	5% CO_2	12% O_2
slope	10% CO_2	0% O_2

Calibrating the Barometer

1. Select **Ready > Settings > Calibration > Barometer**.
2. Read the atmospheric pressure from an external barometer in the lab.

3. Enter the atmospheric pressure reading in mmHg.

   The adjustment range for the barometer is the displayed value ±20 mmHg.

Recalling and Printing Calibration Data

The system maintains a calibration summary for all calibrations within a 24-hour period. You can print a calibration summary either automatically or manually.

Automatically Printing a Calibration Summary

Configure the printer setup options to print the summary every day at the end of the first calibration after 6 AM. See *Setting Printer Options*, page 166.

Manually Printing a Calibration Summary

1. Select **Ready > Settings > Data Recall > Print Cal Summary**.
2. Wait for the printing to complete.
3. Select **Back** to return to the Main Menu screen.

Requesting Additional Calibrations

1. Select **Ready > Settings > Calibration**.
2. On the Calibration screen, select the type of calibration you want to perform.

   Note The system does not allow a partial calibration if a full calibration is due. For example, if you select Full 1 Point when a 2-point calibration is due, the system displays Full 2 point required.

   The header text updates dynamically to inform you which part of the calibration cycle is being carried out, and the parameters updating in real time.

   If the calibration passes, the system returns to the previous screen. A successful, user-requested calibration resets the automatic calibration timer.

3. If you select **Cancel** to end or interrupt a running calibration, or if the calibration fails, the system displays the Calibration Failed/Cancelled screen. The system enters a wash cycle and then returns to the previous screen.

   You can cancel a calibration to run an urgent sample. However, you can postpone the same calibration only twice, after which that calibration has priority. If you chose to interrupt a calibration, it is ready to run a sample in less than 40 seconds.

   Note Raising the probe during the 1-minute countdown to calibration delays the calibration indefinitely.

   See *Diagnosing and Fixing Causes of Calibration Failures,* page 68.

Checking Hct Slope

Note The system automatically carries out 1-point calibrations on the Hct sensor and prompts you for a slope measurement via the Action List (see *Using the Action List to Prompt for Maintenance*, page 77).

1. Select **Ready > Settings > Calibration > Hct Slope**.
2. Following the instructions on the screen, lift the probe to the first position.

WARNING

Open ampules carefully. Use ampule breakers to protect your fingers.

3. When the measurement block light comes on, present the Hct slope solution to the probe and gently push the probe sleeve back.

   The system beeps when the probe sleeve is in the correct position and starts sampling.

4. Hold the Hct slope solution in place until prompted to remove it.
5. Close the probe.

   The system positions the Hct slope solution.

   The system shows the Hct slope result and the confirms the slope measurement is successful.

   Note If Hct slope is not measured within 24 hours of the Action List prompt, all printouts are flagged as Hct slope overdue.

Diagnosing and Fixing Causes of Calibration Failures

1. To print the calibration summary to see possible further details of the problem, select **Ready > Settings > Data Recall > Print Cal Summary**.
2. Review the calibration summary for the following indicators:

Indicator	Calibration or Slope Condition
↑ , ↓	Drift
*	No endpoint
!	Outside range

Note Calibration problems might also be caused by fluidics failures or by hydraulic problems. These conditions do not appear on the calibration summary.

See *Calibration Failures,* page 126 for detailed descriptions of possible causes and corrective actions.

Calibrating the Touch Screen

1. Select **Ready > Settings > Maintenance> Screen Calibration**.
2. Select the **Touch Button** icon in the top, left corner of the screen.

   That icon and label disappear, and a new icon Touch Button appears.
3. Select the **Touch Button** icon in the lower, right corner of the screen.

   The touch screen calibrates and returns to the Operating Setup screen.

6 Quality Control

Siemens recommends that you set up a Quality Control (QC) program to monitor system and operator performance.[4, 5] Because the needs of each laboratory are different, because of patient sample volume, the number of hours worked, and statutory regulations, this guide makes no attempt to formulate a rigid program. Follow your local regulatory guidelines to establish a QC program.

Siemens recommends the use of Siemens-approved QC materials. If you report your results to a quality control statistical program, be sure to include the name of the instrument: Siemens RAPIDLab 348EX system.

Handling QC Samples

1. Follow proper QC sample handling procedures to avoid significant errors in QC measurements.

   Such errors might be caused by any of the following issues:

   - Improper storage and temperature equilibration of the QC sample
   - Improper mixing of the QC sample
   - Contamination of the QC sample by room air
2. Always carefully follow the manufacturer's instructions for use, especially regarding the temperature of the QC material before sampling.
3. Mix the QC material thoroughly, and once the ampule is opened, sample the QC material immediately.
4. Do not re-use an opened ampule.
5. Position the probe near the bottom of the ampule to obtain a representative sample.

Default QC Operating Setup

The default (factory set) QC options and values are as follows:

Element	Value	
pH	6.001–8.000	(10.0–997.7 nmol/L H^+)
pCO_2	5.0–250.0 mmHg	(0.67–33.33 kPa)
pO_2	0.0–749.0 mmHg	(0.00–99.86 kPa)
Na^+	80–200 mmol/L	
K^+	0.50–9.99 mmol/L	
Ca^{++}	0.20–5.00 mmol/L	
Cl^-	40–160 mmol/L	
Hct	12–75%	
QC prompts	not set	

Changing the Default QC Operating Setup

For information about changing the default QC setup, including setting QC prompts, see *QC Ranges Setup, page 164*.

Note Changing the QC setup clears existing results.

Analyzing QC Samples

If QC Prompts have been set, the system prompts you via the Action List to analyze a QC sample. You can also run QC samples at any time from the Ready screen.

1. Select **Ready > QC**.
2. Lift the probe lever to the first position.

   The measurement block light comes on and the touch screen displays the Probe open screen.

CAUTION

Open ampules carefully.

Use ampule breakers to protect your fingers.

3. Present the QC sample to the probe and gently push the probe sleeve back.

   The system beeps and the screen displays the Sampling message when the probe sleeve is in the correct position and starts sampling.

4. Hold the sample in place.

   The system beeps and the screen displays the Sampling complete message when sampling is complete.

5. Remove the sample and close the probe.

   The touch screen displays the **Measuring** screen, overlaid with the **Select QC Level** dialog box.

6. On the Select QC Level screen, select **Level 1**, **Level 2**, **Level 3**, **Hct Level A**, **Hct Level B**, or **Level X**.

   This ensures that the result is compared to the appropriate QC reference range, assigned to the appropriate QC file, and reported correctly on the printer and DMS systems. If you do not select a QC level, the system assumes Level X, which has no range checking.

7. When the measurement is complete, the system displays the results for the appropriate QC Level on 2 successive screens.

   Note If the measured values are outside the configured QC ranges, an arrow indicates whether they are above (↑) or below (↓) the range.

While the results are displayed and printed, the system washes the probe and sample path.

When the wash has finished, the measurement block light goes off and the system returns to the Ready screen.

Note If you have set QC Prompts (see *QC Prompts Setup, page 164*), analyzing a QC sample clears the Action List prompt. If more than one QC prompt has become due, all printouts are flagged as QC overdue.

Recalling and Printing QC Data

The system retains the data for the last 90 QC samples measured for each QC level. The system calculates statistics for QC levels 1, 2, and 3, and for Hct levels A and B.

QC Level X has no statistical data, as that level has no range checking. If no data is available for a selected level, the system briefly displays the No Data Available screen, then returns to the QC Data screen.

Recalling, Viewing, and Printing a QC Result

1. Select **Ready > Settings > Data Recall > QC Data**.

2. Select a QC or Hct level to view the statistics for that level.

   The system displays a screen with a scrolling list of the QC identification data, analysis time and date, QC number, and QC lot for the last QC sample measured.

3. Scroll through the displayed stored results for that level until the identification data for the QC sample you want to recall is visible.
   - Use the scroll bar to scroll through the entire list.
   - Use the up and down arrows at each end of the scroll bar to move the list.

4. Select the result that you want to highlight for further action.

5. Select **View Result** to display the full results QC record for the highlighted result.

6. Select **Move Result** to move the highlighted result to another QC level.

   For example, you might do this if the result was wrongly assigned to a level during measurement. Moving a result to Level X excludes the data from any statistics.

7. On the Select QC Level screen, select the QC level memory location to which to move the result, or select **Cancel** to exit without moving the result.

   After the move, or after timing out, the system returns to the previous screen. If no further results remain in the QC levels memory from which this screen was accessed, then selecting any of the QC level buttons returns the system to the QC Data screen.

8. To print the results, select **Print Result**.

   The printout shows the date and time the QC sample was analyzed, not the time of recall.

   When printing is done, the system returns to the previous screen.

9. Select **Back** to return to the QC Data screen.

Printing a QC Statistical Report

To print all the statistics for all QC levels, select **Ready > Settings > Data Recall > QC Data > Print Statistics**.

The printed statistics are number, mean, SD, and CV% for QC level 1, 2, and 3, and Hct levels A and B.

The system displays Please wait while it calculates the statistics before printing. After printing, the system returns to the QC Data screen.

7 Maintenance

To ensure reliable, trouble-free performance, diligently perform these required regular preventive maintenance routines.

Note The maintenance frequency is based on analyzing 20–30 samples per day. Increase the maintenance frequency if your laboratory analyzes more than 30 samples per day.

Preparations

1. Use the Disinfect routine before carrying out the following maintenance routines. See *Disinfectants to Use with the Disinfect Routine,* page 83:
   - Replacing the pump tubing, cleaning and lubricating the rollers.
   - Replacing the reference sensor cassette.
   - Filling/replacing the pH, Na^+, K^+, Ca^{++}, or Cl^- sensor.
   - Replacing the pCO_2 and pO_2 sensors.
   - Replacing the Hct sensor.
   - Replacing the probe and tubing, probe housing, and probe protector.
   - Replacing the pre-heater tube.
2. Before performing maintenance procedures, suspend the instrument functions using the Stop System routine, page 84.

   If you are carrying out maintenance via the Action List (see *Using the Action List to Prompt for Maintenance,* page 77), the RAPIDLab 348EX system automatically suspends instrument functions.
3. When replacing the pump tubing and bottle tubing, drain the system. See *Using the Prime Routine,* page 85.

The system logs maintenance tasks, including the Deproteinize, Condition, Prime, Disinfect, and Stop System routines on the printout. The printout also shows if the electrode block door was opened during a calibration or during sample or QC measurements, or if the power was turned off and on.

Accessing Maintenance Functions

1. Select **Ready > Settings > Maintenance**.
2. Select the function you want to perform.

Daily Maintenance

Equipment:

- Buffer Pack, as required
- Wash Pack, as required

- 10% v/v bleach
- Clean tissues

1. Check levels of reagents and replace if necessary. See *Checking the Reagents,* page 79.

   With typical use, the reagents need replacing every 10 to 14 days. Replace the reagents after 21 days of use.

2. Agitate the buffer pack daily to incorporate any solution that may have condensed on the inside of the bottles.
3. Check the waste bottle and empty if necessary. See page 78.
4. Wipe the probe sleeve, sample area, reagent compartment, and external surfaces with clean tissues moistened with 10% v/v bleach.

   Do not spray into the measurement block.

   Note Do not use any cleaning material containing alcohol, as this could cause certain components to crack.

5. Clean the drip tray.

   Verify that it is located properly and that the connector is fitted, *Cleaning or Replacing the Drip Tray,* page 102.

6. Verify that the printer has enough paper.

   If the red stripe is showing, replace the paper, page 102.

Weekly Maintenance

Equipment:

- Same as for daily maintenance, plus disinfectant, as required
- pH fill solution
- $Na^+/K^+/Ca^{++}/Cl^-$ fill solution
- Reference fill solution, as required

1. Carry out daily maintenance and use the Disinfect routine (page 83).
2. Check the level of fill solution in the sensors:
   - The reference sensor should be filled to the line.
   - The pH, K^+, Ca^{++} (or Cl^-) sensors should be almost full, with only a small bubble at the top
   - The Na^+ sensor should be full.
3. Refill the sensors if necessary. See *Refilling or Replacing the Measurement Sensors,* page 94.

Note The Hct sensor does not have fill solution. The pCO_2 and pO_2 sensors contain fill solution, but cannot be refilled. Slight discoloration of the fill solution in these sensors is normal.

4. Check the sensors for air bubbles in the fill solution.

   If necessary, remove the sensors and tap to dislodge air bubbles. See *Refilling or Replacing the Measurement Sensors,* page 94.

5. Check the reference sensor for bubbles in the fill solution and for crystal growth.
   a. If air bubbles are present, remove the sensor and tap it to dislodge air bubbles.
   b. If crystal growth is present, remove the sensor, empty the fill solution, and rinse with deionized water, then refill the sensor with reference sensor fill solution.
   c. Clean off excess fill solution using lint-free tissue and deionized water.
   d. Push a clot removal line into the vent hole to clear any fill solution crystals.

   See *Replacing the Reference Sensor Cassette or Inner Electrode,* page 97, for details.

Every-Other-Week Maintenance (or as Prompted via the Action List)

Equipment:

- Same as for daily and weekly maintenance
- User Action Pack, or Deproteinizer, Conditioner, and Hct Slope

1. Carry out daily and weekly maintenance.
2. Deproteinize and condition the sensors. See *Deproteinizing the Sensors,* page 81 and *Conditioning the Sensors,* page 82.

   Note Depending on the way the system is configured, deproteinizing and conditioning might be prompted more frequently than once every two weeks - see *Setting the Maintenance Prompts,* page 168.

3. Carry out an Hct slope check. See *Checking Hct Slope,* page 67.

   The instrument prompts for an Hct slope check after every Deproteinize routine.

Quarterly Maintenance

Equipment:

- Same as for daily, weekly, and every-other-week maintenance
- Pump tubing kits
- Screwdriver
- Mild detergent
- Dip tray, as required

1. Carry out daily, weekly, and every-other-week maintenance.
2. Replace the pump tubing and the pump rotor mouldings. See page 89.
3. Clean and lubricate the pump roller assembly. See page 91.
4. Date the pump tubing labels a maximum of 3 months ahead.

   Note Under heavier workload conditions, replace the pump tubing more frequently.
5. Replace the drip tray if it is becoming difficult to clean. See *Cleaning or Replacing the Drip Tray,* page 102.

Six-month Maintenance

Equipment:

- Same as for daily, weekly, every-other-week, and quarterly maintenance
- Bottle tubing kit

1. Carry out daily, weekly, every-other-week, and quarterly maintenance.
2. Replace the bottle tubing. See page 101.

Using the Action List to Prompt for Maintenance

You can choose how often some Action List prompts appear for Deproteinize, Condition, QC, and Waste Bottle. See *Setting the Maintenance Prompts,* page 168.

Other prompts—those for Sensors, Hct Slope, Gas, and Printer—appear when the system detects that user action is required.

Note When the Action List prompts you to replace the gas cartridges or empty the waste bottle, the system temporarily suspends its functions, so that you can perform those actions without using the Stop System routine.

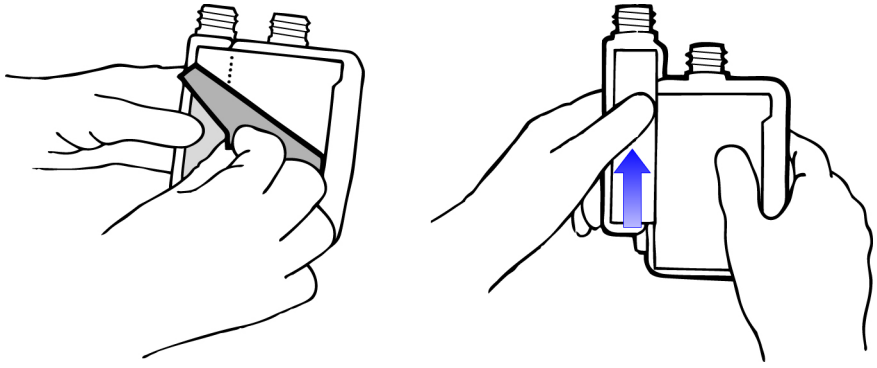
Emptying the Waste Bottle

BIOHAZARD

See *Section 4, Safety Information*, for recommended precautions when working with biohazardous materials.

1. Select **Action List > Waste Bottle**.
2. Remove the waste bottle:
   a. Lift the front cover.
   b. Carefully pull the waste bottle forwards, tilting the top slightly away from you.
3. Cap the waste bottle and dispose of it in accordance with your laboratory guidelines.
4. Prepare an empty wash bottle or an empty 7.3 buffer bottle from the Buffer Pack for use as the new waste bottle:
   a. Peel off the top label from the top, right corner to expose the waste label.
   b. To use the 7.3 buffer bottle, separate the label at the perforation.
   c. Slide the 6.8 buffer bottle off and discard (*Figure 3*).

Figure 3: Separating Buffer Bottles



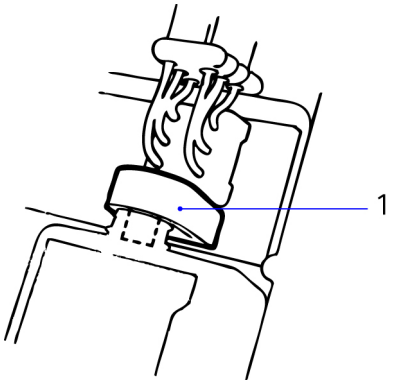
Note Siemens recommends that you put approximately 10 mL of disinfectant or sodium hypochlorite into the waste bottle before placing it in position.

5. Replace the waste bottle:
   a. Tilt the top of the bottle away from you and slide the bottle into position.

b. Verify that the neck of the waste bottle is positioned underneath the rubber cap.

   The waste cap spout should be inside the neck of the waste bottle.

Figure 4: Replacing the Waste Bottle



1. Waste cap spout

6. Lower the cover.
7. Clear the Waste Bottle prompt by selecting **Waste bottle**.
8. Continue with further actions or select **Back** to exit to the Ready screen.
9. Discard the waste bottle and its contents according to your laboratory protocol. CLSI Publication GP05-A3 (Electronic Document) *Clinical Laboratory Waste Management* gives detailed guidelines.[3]

Checking the Reagents

1. Check the reagent levels and change-by date regularly.
2. If either of the Buffer pack bottles or if the Wash bottle is empty, or if the Buffer pack is past the change-by date, replace it as follows.

Changing the Reagents

Equipment:

- 6.8/7.3 Buffer pack
- Wash pack

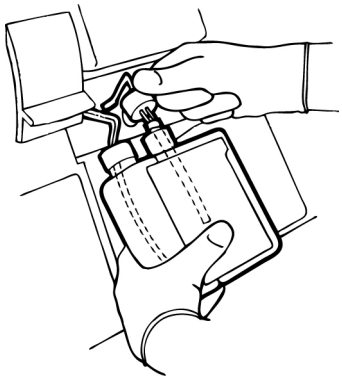
1. Stop the system by selecting **Ready > Settings > Maintenance > Stop System**.

2. Wait for the System Stopped message.
3. Raise the front cover and remove and save the empty bottles for use as new waste bottles.

   See *Emptying the Waste Bottle,* page 78, for details about reusing these bottles.
4. Remove the cap from the replacement bottle.

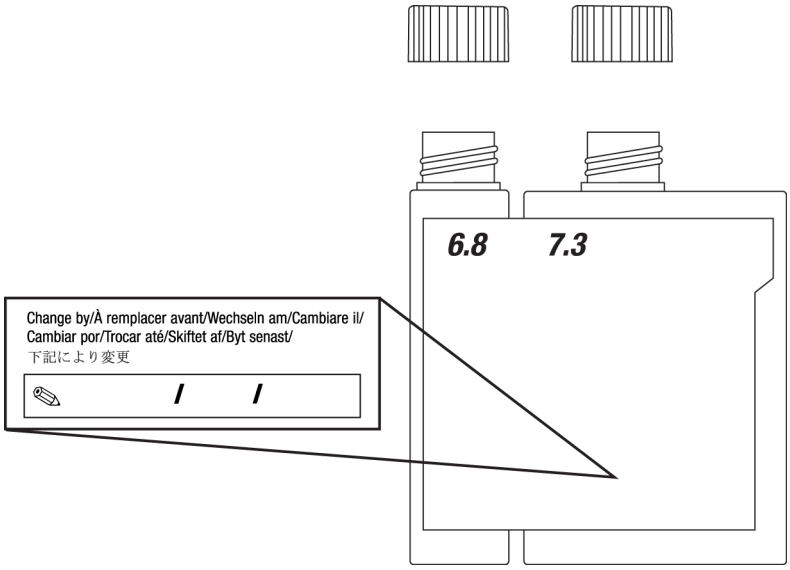
   Retain the cap for use when replacing the waste bottle.
5. Feed the bottle tubing into the neck of the bottle and into the solution.
6. Tilt the top of the bottle slightly away from you and slide it into position.

Figure 5: Positioning the Reagents



7. Press the cap firmly onto the neck of the bottle.
8. If you are changing the buffer bottles, date the label 21 days ahead.

Figure 6: Dating the Buffer Label



9. Lower the front cover and select **Restart** to restart the system.
10. Select **Ready > Settings > Maintenance > Prime**.
11. When the Prime routine has finished pumping the new reagents through the system, select **Back** twice to exit.

    The system calibrates on return to the Ready screen.

Deproteinizing the Sensors

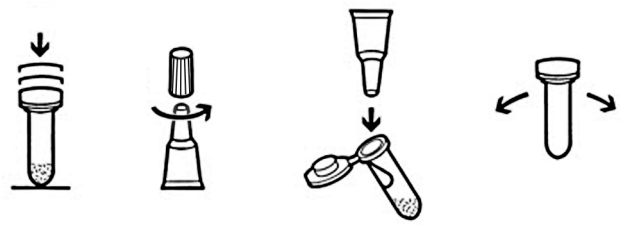
Equipment: User Action Pack or Deproteinizer

You can deproteinize the system when you get an Action List prompt or at any time via the Maintenance menu.

1. Activate the Deproteinizer by mixing D1a and D1b:
   a. Tap the vial (D1b) before opening to return all the pepsin powder to the bottom of the vial.
   b. Gently add solution D1a.
   c. Cap and shake the vial until the powder has dissolved.

      This takes a few seconds. The powder must be completely dissolved before using the solution.

Figure 7: Activating the Deproteinizer



2. Select **Action List > Deproteinze**, or **Ready > Settings > Maintenance > Deproteinize**.
3. Following the instructions on the screen, lift the probe to the first position and present the deproteinizing solution.
4. Hold the solution in place until prompted to remove it, then close the probe.
5. Wait while the system performs the deproteinizing routine.

   The deproteinizer remains in contact with the sensors for 5 minutes, and the screen shows the time remaining. When deproteinizing is finished, the system washes and calibrates on return to the Ready screen. The system prompts for an Hct slope after a deproteinizing routine.
6. To cancel the Deproteinize routine to measure a sample, select **Cancel**.

   The system washes and calibrates on return to the Ready screen.

Conditioning the Sensors

Equipment: User Action Pack or Conditioner

Note Only the glass sensors (pH and Na^+ sensors) require conditioning.

You can condition the sensors when you get an Action List prompt or at any time via the **Maintenance** menu.

1. Select **Action List > Condition**, or select **Ready > Settings > Maintenance > Condition**.
2. Following the instructions on the screen, lift the probe and present the conditioning solution.
3. Hold the solution in place until prompted to remove it, then close the probe.

   The Conditioner remains in contact with the sensors for 5 minutes, and the screen shows the time remaining. When conditioning is finished, the system washes and calibrates on return to the Ready screen.

4. To cancel the **Condition** routine to measure a sample, select **Cancel**. The system washes and calibrates on return to the **Ready** screen.

Disinfectants to Use with the Disinfect Routine

BIOHAZARD

See *Section 4, Safety Information*, for recommended precautions when working with biohazardous materials.

CAUTION

Use disinfectant in accordance with the manufacturer's instructions. Siemens cannot accept responsibility for the effectiveness of the disinfectant used with the Disinfect routine.

We have tested the following disinfectants for compatibility with our sensors:

- 1% or 2% Virkon
- 10% v/v bleach

CAUTION

Both Virkon and 10% v/v bleach affect the reference sensor. To prevent damaging the reference sensor, if you use either of these two disinfectants, you must remove the reference sensor and replace it with an old sensor. Alternatively, use a Test blank sensor - ref (TB5).

Using the Disinfect Routine

The **Disinfect** routine pumps disinfectant through the probe and sample path and leaves it in place for 10 minutes.

CAUTION

Perform the Disinfect routine before replacing the pump tubing, sensors or the probe and tubing, and after analyzing a sample known or suspected to contain dangerous pathogens.

Note To prevent protein fixation, we recommend deproteinizing the system (page 81) before using the Disinfect routine.

Equipment:

- Bleach or Virkon solution

- Test blank sensor, as required

CAUTION
Always observe good laboratory practices when handling any component of the system under biohazardous conditions.

1. Select **Ready > Settings > Maintenance > Disinfect**.
2. Following the instructions on the screen, lift the probe to the first position and present the disinfectant.
3. Hold the solution in place until prompted to remove it, then close the probe.

   The disinfectant remains in the measurement block for 10 minutes, and the screen shows the time remaining. When the routine is finished, the system washes and calibrates on return to the Ready screen.
4. To cancel the Disinfect routine to measure a sample, select **Cancel**.

   The system washes and calibrates on return to the Ready screen.
5. Preferably, remove the probe and tubing, page 106, measurement block tubing, page 106, and sample pump tubing, page 89, and replace them with new tubing.

   Note Alternatively, you can soak these tubes for 10 minutes in 10% v/v bleach and replace them, but replacing them with new tubing is preferable.

Stopping the System

The Stop System routine suspends instrument functions, such as calibrations, while you are carrying out routine maintenance such as changing the reagents, sensors, pump tubing, and bottle tubing, or clearing blockages.

CAUTION
Do not leave the system stopped for longer than necessary, as this might damage the sensors and pump tubing.

1. From Ready select **Menu.**
2. Select **Maintenance**.
3. Select **Stop System**.

   If the beeper is enabled, the system beeps once per second after 30 minutes in Stop System.

4. Perform the maintenance task.
5. To quiet the beeper, if necessary, select **Cancel Beeper** when that option appears.
6. Select **Restart** to restart the system.

Using the Prime Routine

The Prime routine drains and pumps solution and gases through the system. Use the Prime routine when replacing the pump tubing, changing reagents, or pumping disinfectant through the manifold.

Note If you are changing the gas cartridges, it is not necessary to drain the system.

Draining the System

1. Raise the front cover and remove the Buffer pack and Wash bottle.

   Do not remove the Waste bottle.
2. Place tissues under the bottle tubes to catch any spillage.
3. Select **Ready > Settings > Maintenance > Prime**.

   The system pumps and drains the system.

Priming the System

1. Perform the appropriate maintenance procedure.
2. Select **Ready > Settings > Maintenance > Prime**.

   The system primes.
3. After the system primes, select **Back** twice to return to the Ready screen.

Changing the Gas Cartridges

CAUTION

- Use only Siemens gas cartridges supplied for use with the system, as they have been designed for ease of use and optimum performance.
- Siemens assumes no liability for performance if cartridges other than those specified for use with the system are used.

WARNING

Compressed gas cartridges require careful handling. To prevent damage and possible personal injury, observe the following precautions:

- Never install other gases, for example, propane cartridges.
- Never drop cartridges, allow them to strike each other or subject them to other strong shocks.
- Never tamper with the cartridge valves.
- Use these gases only for the calibration of clinical and research instrumentation. (US Law prohibits dispensing these gases for drug use.)
- Do not puncture the cartridges. The contents are under pressure.
- Do not use or store near heat or open flame.
- Do not expose cartridges to temperatures above 54°C (130°F) as this may cause the contents to vent or explode.
- Never throw cartridges into fire or incinerators. Dispose of the empty cartridges following your laboratory protocol.

Equipment:

- Gas cartridge pack
- Gas cartridge removal tool and Gas cartridge venting tool

The system detects when the gas pressure is low and prompts you to change the gas cartridges via the Action List.

Note When the gas low prompt appears, less than 5% of the gas remains, and you can safely dispose of the cartridges.

1. Select **Ready > Action List > Gas**.

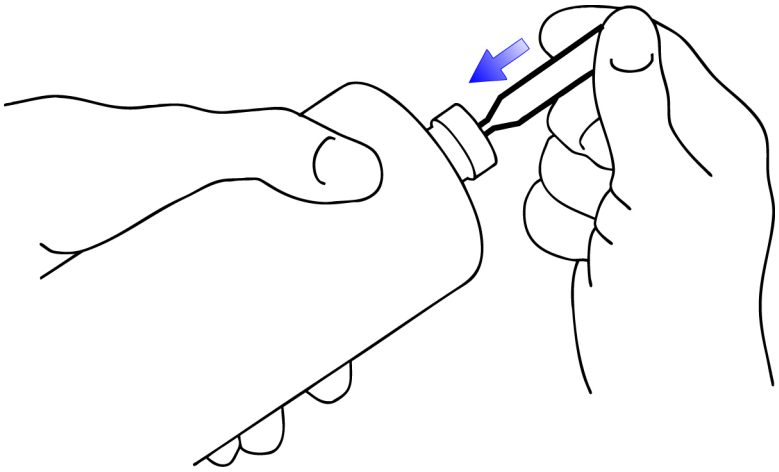
   Note Always replace both gas cartridges.

2. Unscrew the gas cartridges by turning them in a counterclockwise direction, using the removal tool if necessary.

3. Slide both cartridges out of the gas cartridge compartment.
4. If required, vent any remaining gas using the venting tool:
   a. Remove the cartridge to a well ventilated area.
   b. Point the cartridge away from yourself, and from other people.
   c. Insert the venting tool as shown.

      You might hear a slight hiss as the gas vents.

Figure 8: Venting the Gas Cartridges



5. Dispose of the empty gas cartridges according to your laboratory protocol.
6. Install the new cartridges:

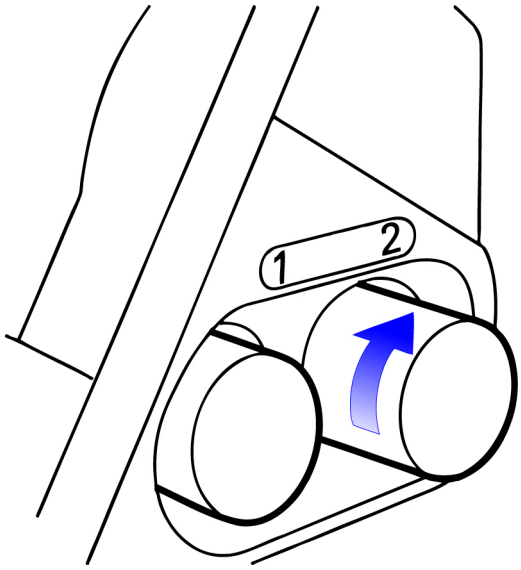
CAUTION

The cartridges and cartridge compartment are clearly marked and color coded: gas 1 (blue) and gas 2 (black). See *Figure 9*. Make sure the cartridges are installed in the correct position.

   a. Remove the plastic protective cap from the cartridge valve.
   b. Slide the cartridge into the compartment, and then gently push and turn the cartridge clockwise to engage it with the regulator.
   c. Screw the cartridge in until finger tight.

Note The gas regulator assembly is designed to make a good seal by finger tightening only. Do not overtighten the cartridges, either by using tools or by applying excessive force.

Figure 9: Changing the Gas Cartridges



7. Prime the system. See *Priming the System,* page 85.

Checking the Gas Flow Rate

1. Initiate a full 2-point calibration by selecting **Ready > Settings > Calibration > Full 2 Point**.

   The system checks the gas flow rate while measuring the gas.

2. When the calibration gas values appear on the display, lift the probe lever to the first position.
3. Fit a capillary adaptor to the end of the probe.

   This makes the bubbles easier to count.

4. Present a small beaker of deionized water to the probe and count the bubbles for at least 15 seconds.

   The bubble rate should be greater than 5 bubbles/15 seconds (20 bubbles/minute)

5. Remove the capillary adaptor and close the probe.
6. When the slope gas values appear on the display, lift the probe and repeat steps 2 through 5 for the slope gas.
7. If either of the gas flow rates is incorrect, contact your local technical provider or distributor.

Changing the Pump Tubing and Cleaning and Lubricating the Rollers

BIOHAZARD

See *Section 4, Safety Information*, for recommended precautions when working with biohazardous materials.

Equipment:

- Pump tubing kits
- Screwdriver
- Mild detergent
- Disinfectant

The system has 2 sets of pump tubes: the sample pump tubing (2 tubes), on the left, and the reagent tubing (3 tubes), on the right. For optimum performance, change both pump tubing kits together, on or before the dates shown on the label.

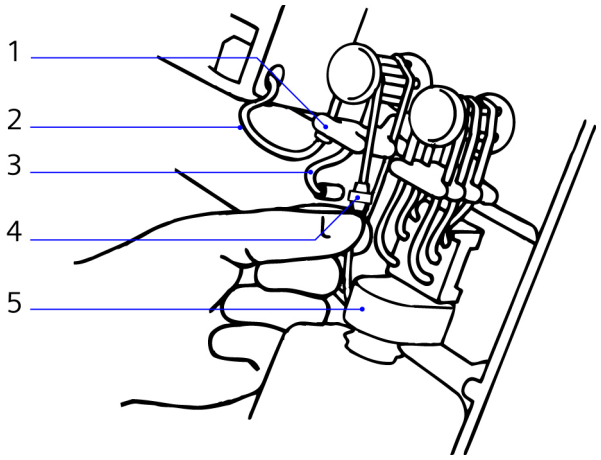
Changing the Pump Tubing

1. Use the Disinfect routine, then drain the system. See *Using the Disinfect Routine,* page 83 and *Draining the System,* page 85.
2. Stop the system. See *Stopping the System,* page 84.

Changing the Sample Pump Tubing

1. Remove the waste bottle.
2. Disconnect the waste cap connector from the manifold.
3. Disconnect the sample tube from the measurement block tube, and the waste tube from the manifold.
4. Release the tension on the tubes by pulling each tube down and to the side until the lug is clear of the tensioner.
5. Remove the pump tubing.

Figure 10: Removing the Sample Pump Tubing

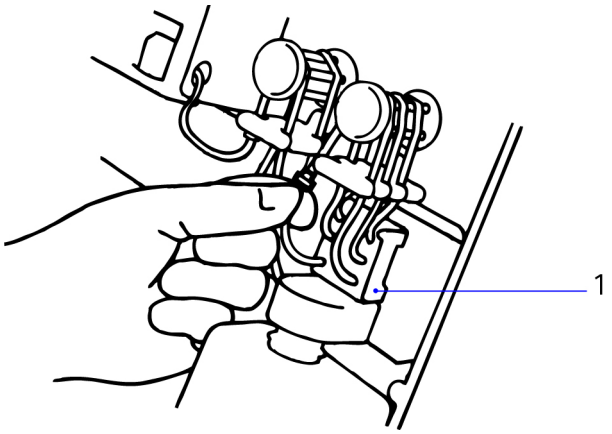


1. Tensioner
2. Measurement Block Tube
3. Waste Tube
4. Lug
5. Waste Cap Connector

Changing the Reagent Pump Tubing

1. Disconnect the rubber connector from the manifold.
2. Release the tension on the tubes by pulling each tube down and to the side until the lug is clear of the tensioner.
3. Remove the reagent pump tubing, *Figure 11*.

Figure 11: Removing the Reagent Pump Tubing



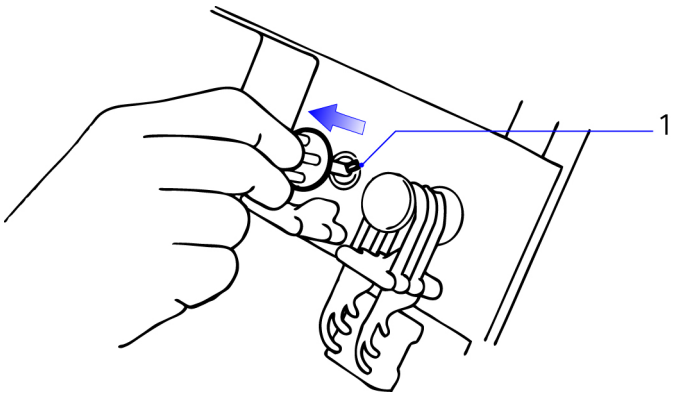
1. Rubber Connector

Cleaning the Rollers

1. Remove the finger screw holding the pump rotor in place and slide the rotor off the moulding.

   Note The drive pin, *Figure 12*, might drop out.

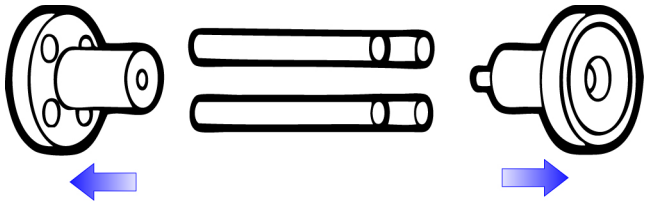
Figure 12: Removing the Pump Rotor



1. Drive Pin

2. Remove the pump rotor mouldings by pulling the pump rotor ends apart. See *Figure 13*.

Figure 13: Removing the Pump Rotor Mouldings

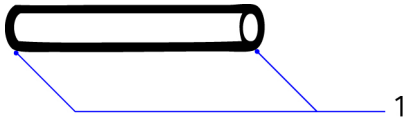


3. Wash the rollers in mild detergent solution, rinse, and dry with tissues.

Lubricating the Rollers

1. With the grease supplied, lightly lubricate each roller at the points shown in *Figure 14*.

Figure 14: Lubricating the Rollers



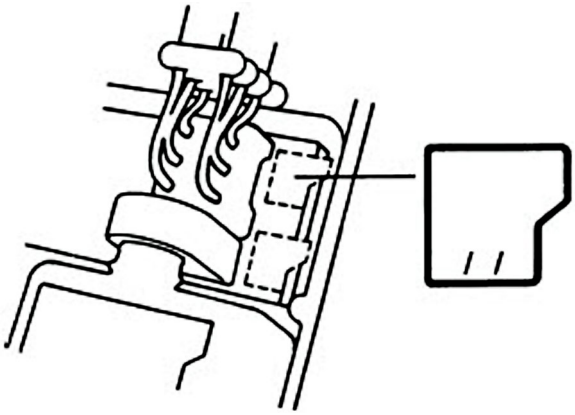
1.	Lubrication Points

2. Re-assemble the rotor using the new pump rotor mouldings.
3. Replace the pump rotor.
4. Make sure the drive pin is located correctly.

Installing New Pump Tubing

Date the label a maximum of 3 months ahead. See *Figure 15*.

Figure 15: Dating the Pump Tubing Label



Installing New Sample Pump Tubing

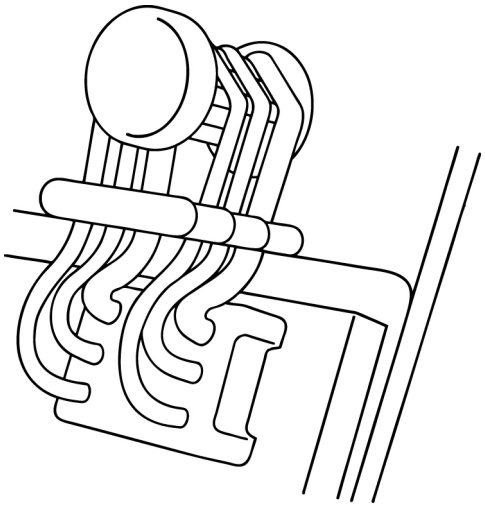
1. Install the new sample pump tubing:
   a. Connect the waste cap connector to the manifold.
   b. Push firmly into position.
2. Place the pump tubes over the rotor.

   The tube with the grey connector goes in the back position.
3. Connect the back tube to the manifold.
4. Connect the front tube to the measurement block tube.
5. Pull the tube lugs underneath the tensioners.
6. Replace the waste bottle.

Installing New Reagent Pump Tubing

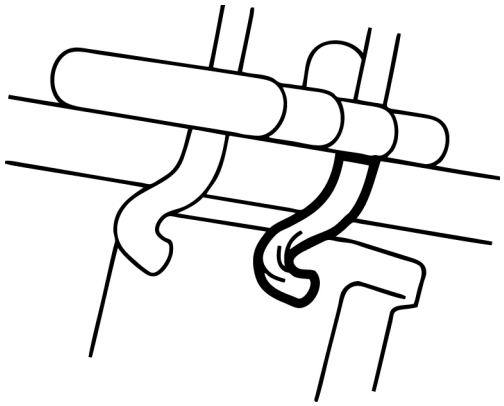
1. Install the new reagent pump tubing:
   a. Loop the pump tubes over the rotor.
      The thick tube goes in the back position.
   b. Pull the tube lugs underneath the tensioners.
   c. Connect the rubber connector to the manifold.
   d. Push the connector firmly into position.
   e. See *Figure 16* to make sure the tubes are fitted correctly.

Figure 16: Reagent Pump Tubing Correctly Installed



2. Ensure that no pump tubes are pinched or twisted. See *Figure 17*.

Figure 17: Example of Twisted Tube



3. Replace the reagent bottles, lower the front cover, and restart the system.
4. Prime the system. See *Priming the System,* page 85.

Refilling or Replacing the Measurement Sensors

BIOHAZARD
See *Section 4, Safety Information*, for recommended precautions when working with biohazardous materials.

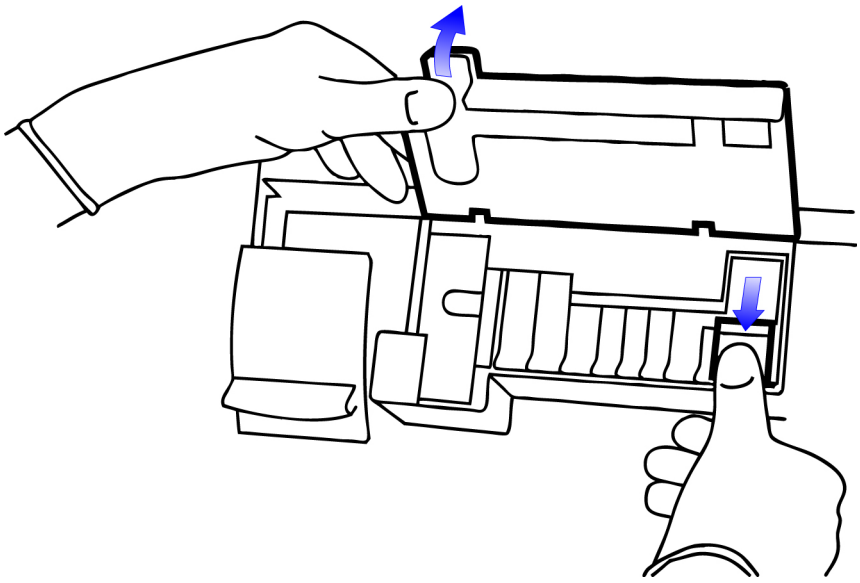
Equipment:

- pH fill solution, as required
- $Na^+/K^+/Ca^{++}/Cl^-$fill solution, as required
- Replacement sensors, as required
- Disinfectant

Note Although the pCO_2 and pO_2 sensors contain fill solution, they cannot be refilled. To replace the pCO_2 and pO_2 sensors, or the Hct sensor, follow the instructions in steps 1–5 and 8–10.

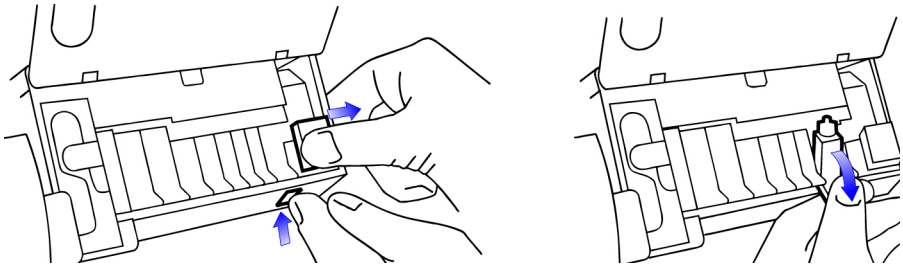
1. Use the Disinfect routine. See *Using the Disinfect Routine,* page 83.
2. Stop the system. See *Stopping the System,* page 84.
3. Raise the front cover.
4. Slide the measurement block catch down and raise the block door. See *Figure 18*.

Figure 18: Opening the Measurement Block Door



5. Swing the tensioner to the right and press the tensioner lock button to hold the tensioner in the open position.
6. Remove the appropriate sensor. See *Figure 19*.

Figure 19: Removing a Sensor



Refilling the pH, Na^+, K^+, Ca^{++}, or Cl^- Sensor

CAUTION

- Make sure you use the correct fill solution - pH fill solution for the pH sensor, and $Na^+/K^+/Ca^{++}/Cl^-$fill solution for the Na^+, K^+, Ca^{++}, or Cl^- sensor. Do not use reference sensor fill solution.
- Do not touch the inner electrode as it is fragile and easily damaged.

1. Referring to *Figure 20, Refilling the pH/Na^+/K^+/Ca^{++}/Cl^- Sensor* , unscrew the inner electrode and set it aside on lint-free tissue.

2. Empty the fill solution out of the sensor.
3. Fit a needle to the fill solution container, rinse out the sensor body with a few drops of fill solution and refill the sensors almost full, leaving a small bubble at the top.
4. Tap the sensor during filling to dislodge air bubbles.

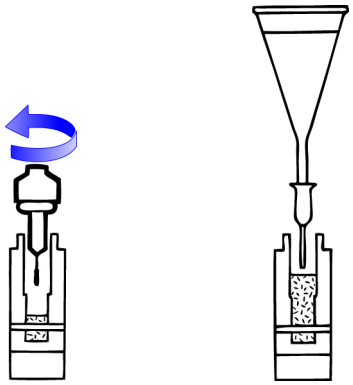
   Note If you are refilling the Na^+ sensor, fill to the top. Do not leave an air bubble.

5. Replace the inner electrode.

   Screw the electrode down tightly. Be careful not to cross-thread the electrode.

6. Shake the sensor down by holding it in your hand and flicking your wrist several times to dislodge air bubbles at the sensor capillary.

Figure 20: Refilling the pH/Na^+/K^+/Ca^{++}/Cl^- Sensor



7. Wipe the sensor with dry, lint-free tissue and verify that the O-ring is in position on the left side, and is in good condition.
8. Tap the sensor to release any trapped air bubbles.

Reinstalling the Sensor

1. Install the sensor top first, aligning the sensor contacts.
2. Press the bottom of the sensor into position.
3. Hold the tensioner and press the tensioner lock button.
4. Gently release the tensioner and push it firmly home to make a good seal.
5. Lower the block door, snapping it into place.
6. Lower the front cover.

7. Select **Restart** to restart the system.

   The system calibrates on return to the Ready screen.

Note Siemens recommends that you use the condition routine after refilling or replacing a pH or Na^+ sensor.

A new sensor might take up to 90 minutes to stabilize. The system deselects a sensor if it fails calibration, but monitors it and automatically reselects it when it meets calibration specifications.

Replacing the Reference Sensor Cassette or Inner Electrode

BIOHAZARD

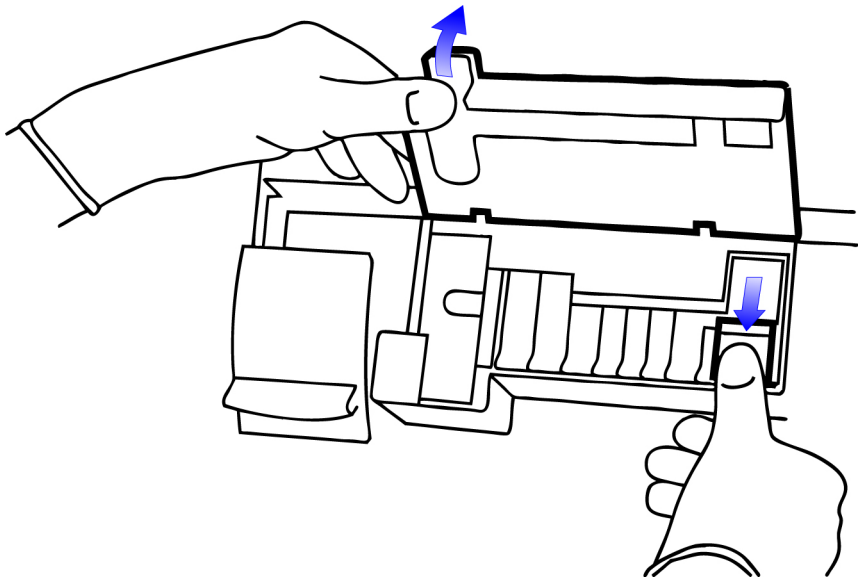
See *Section 4, Safety Information*, for recommended precautions when working with biohazardous materials.

Equipment:

- Reference sensor cassette, as required
- Reference inner electrode, as required
- Disinfectant
- Clot removal line

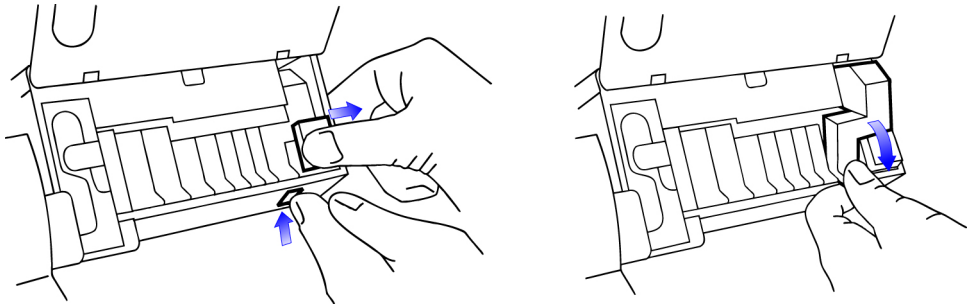
1. Use the Disinfect routine. See page 83.
2. Stop the system. See page 84.
3. Raise the front cover.
4. Slide the measurement block catch down and raise the block door.

Figure 21: Opening the Measurement Block Door



5. Swing the tensioner to the right and press the tensioner lock button to hold the tensioner in the open position.
6. Remove the reference sensor (*Figure 22*).

Figure 22: Removing the Reference Sensor



CAUTION

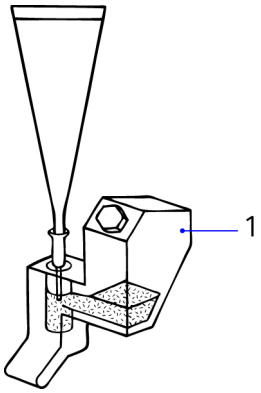
Make sure you use reference fill solution. Do not use pH or $Na^{+}/K^{+}/Ca^{++}/Cl^{-}$ sensor fill solution.

CAUTION

Do not touch the reference inner electrode, as it is fragile and easily damaged.

7. Replace the reference sensor cassette:
   a. Break the top off the reference fill solution container, and fit the needle.
   b. Slowly inject solution into the internal reference compartment of the new cassette.
   c. Continue filling until the liquid level is flush with the sensor reservoir (*Figure 23*).

Figure 23: Filling the Internal Reference Compartment

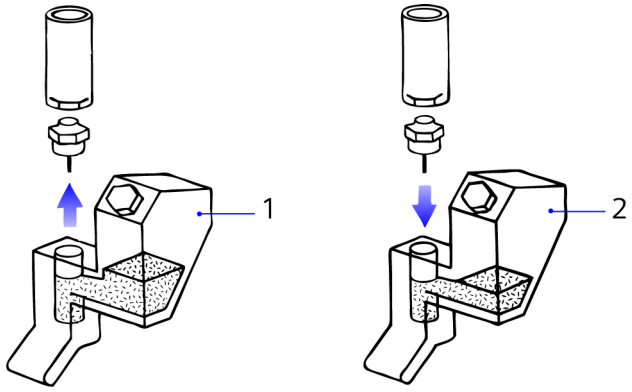


1.	New Cassette

   d. Use the hex tool supplied to remove the reference inner electrode and reservoir cap.
   e. Remove the inner electrode from the old cassette, or, if you are installing a new reference inner electrode, remove it from its container, and screw it into the new internal reference compartment.

      Do not cross-thread the inner electrode (*Figure 24*).

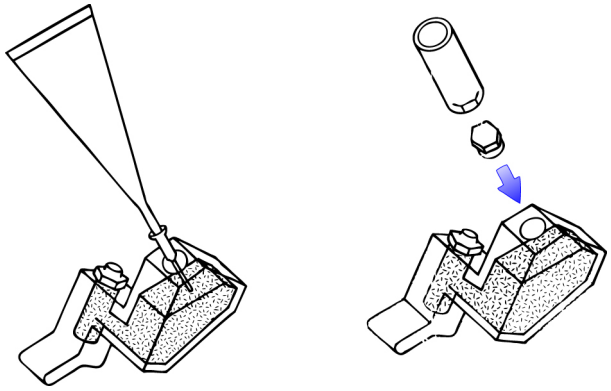
Figure 24: Changing the Reference Inner Electrode



1.	Old Cassette
2.	New Cassette

f. Inject the remaining fill solution into the reservoir up to the fill line and replace the reservoir cap until finger tight (*Figure 25*).

Figure 25: Filling the Reference Reservoir and Replacing the Cap



g. Tilt the reference cassette and tap the front with your knuckle to remove air bubbles.

h. Carefully clean off any excess fill solution using clean lint-free tissue and deionized water.

i. Push the clot removal line through the vent hole to clear any fill solution crystals.

8. Verify that O-rings are fitted to each side of the sensor and are in good condition.

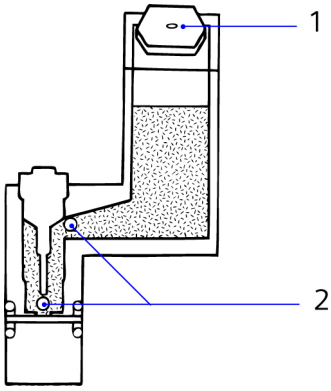
9. Refit the reference sensor top first, aligning the sensor contacts.

10. Press the bottom of the sensor into position.
11. Make sure all the sensors are seated correctly.
12. Hold the tensioner and press the tensioner lock button.
13. Gently release the tensioner and push it firmly home to make a good seal.
14. Lower the block door, snapping it into place.
15. Lower the front cover.
16. Select **Restart** to restart the system.

    The system calibrates on return to the Ready screen.

Note Following a change of reference sensor cassette or inner electrode, it is normal for the system to require a stabilization period of 30 minutes before attaining optimum performance. If an over- or under-range condition is present on the pH and electrolyte channels, an air bubble is probably trapped in the reference sensor (*Figure 26*). Remove the sensor and tap it until the air bubble is dislodged. Re-install the sensor.

Figure 26: Trapped Air Bubble in Reference Sensor



1.	Vent Hole
2.	Trapped Air Bubble

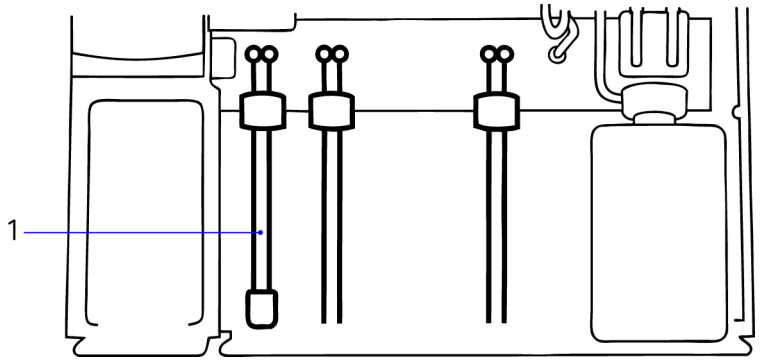
Replacing the Bottle Tubing

Equipment: Bottle tubing kit

1. Drain the system. See *Draining the System*, page 85.
2. Stop the system. See *Stopping the System*, page 84.

3. Disconnect the three sets of bottle tubing from the manifold. See *Figure 27*.
4. Install the new bottle tubing, making sure that the 6.8 bottle tubing is fitted in the correct position.

Figure 27: Changing the Bottle Tubing



1. 6.8 Bottle Tubing

5. Replace the Buffer Pack and Wash bottle:
   a. Feed the bottle tubing into the neck of the bottles and into the solution.
   b. Tilt the top of the bottle slightly away from you and slide it into position.
6. Lower the front cover and select **Restart**.
7. Prime the system, page 85.

Cleaning or Replacing the Drip Tray

BIOHAZARD
See *Section 4, Safety Information*, for recommended precautions when working with biohazardous materials.

Equipment:

- Drip tray
- Disinfectant

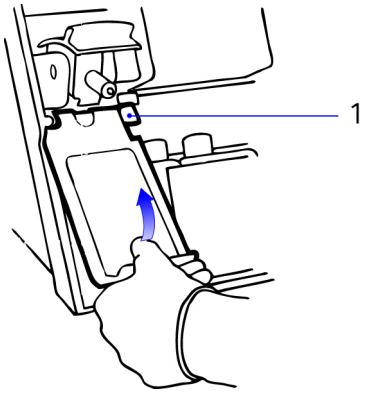
1. Stop the system. See page 84.
2. Raise the front cover.
3. Lift the probe lever to the second position.

4. Disconnect the drip tray connector from the manifold.

   The drip tray is held in place by a magnet, and you will feel some resistance as you remove it.

5. Hold the drip tray at the bottom and pull upwards and out (*Figure 28*).

Figure 28: Removing the Drip Tray



1. Drip Tray Connector

CAUTION

The drip tray is not designed to be autoclaved and reused.

6. Clean the drip tray with disinfectant.

   Replacement drip trays are available (see *Appendix 16, Orderable Supplies*) if it becomes difficult to clean.

7. Refit the drip tray, making sure the connector is reconnected to the manifold.

WARNING

Do not operate the system without the drip tray in place. The drip tray is designed to contain any blood drips, and to keep the probe clean. Failure to install it could result in a build up of blood deposits, and a potentially biohazardous situation.

8. Lower the front cover and restart the system.

Replacing the Printer Paper

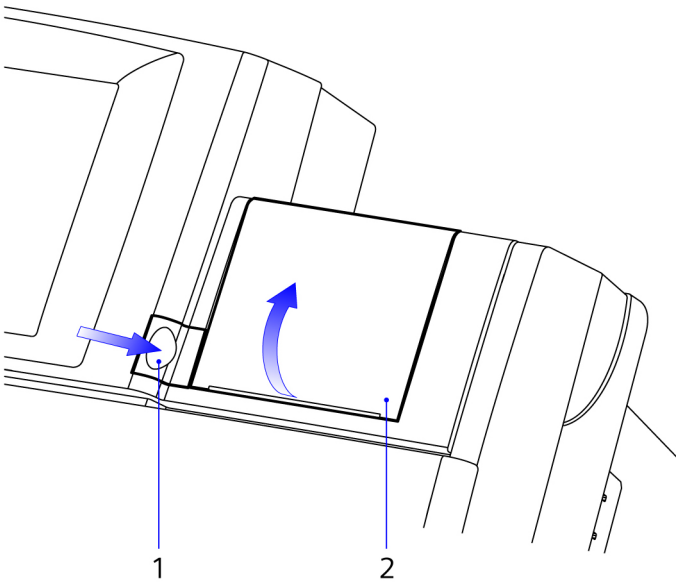
Equipment: Printer paper

CAUTION
Use only Siemens printer paper. Other paper might affect print quality or damage the printer.

Note Replace the printer paper when the red stripe appears or when prompted by the system via the Action List.

1. Press the printer cover release button to open the printer cover (*Figure 29*).

Figure 29: Opening the Printer Cover



1. Printer cover release button
2. Printer cover

2. Tilt the paper compartment cover backwards.
3. Tear off any remaining paper, and remove the old paper roll.
4. Hold the new paper roll in one hand with the paper coming from the bottom of the roll and towards you.

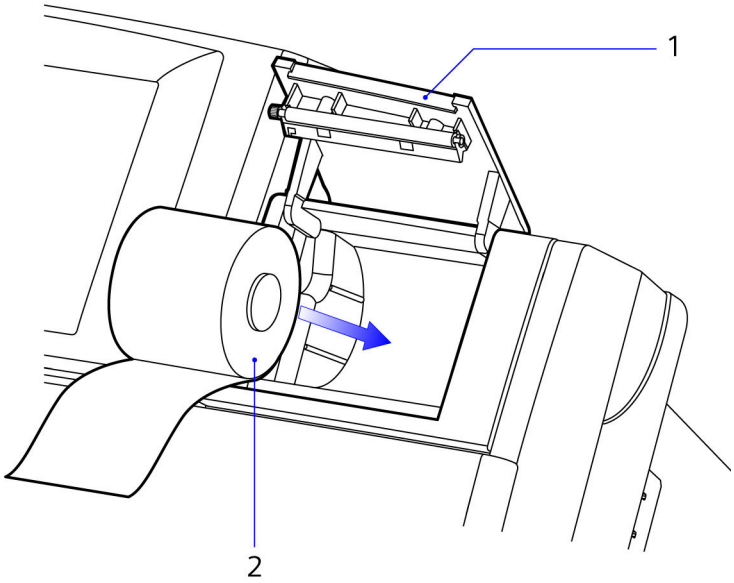
5. Bend the end of the paper back slightly.

CAUTION

Make sure you feed the paper correctly. If the paper is fed in incorrectly, the printer will not print, and it might cause paper jams.

6. Insert the new paper roll into the compartment, making sure that the paper is square to the printer and that at least 5 cm (2 inches) of the paper protrudes from the roll (*Figure 30*).

Figure 30: Loading the Printer Paper



1. Printer cover
2. Thermal paper roll

7. Firmly close the paper cover.
8. Test the printer, to check that the printout is clear.

   Do not forcefully pull the thermal paper, as severe damage might occur. If a problem exists, see *Printer Issues,* page 143 for troubleshooting information.

Replacing the Probe and Tubing and Probe Housing

BIOHAZARD

See *Section 4, Safety Information*, for recommended precautions when working with biohazardous materials.

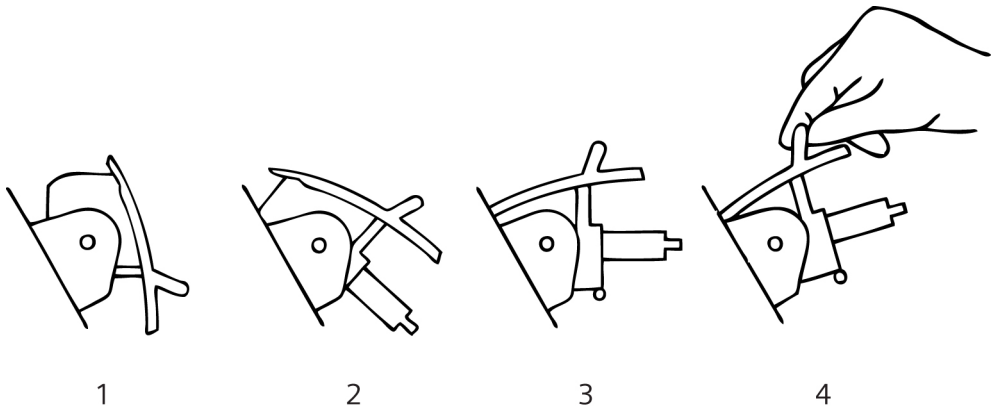
Removing the Current Probe, Tubing, and Housing

Equipment:

- Probe and tubing kit or Probe and housing kit, as required
- Disinfectant

1. Use the Disinfect routine and then stop the system, page 83 and page 84.
2. Raise the front cover.
3. Lift the probe lever to the second position (*Figure 31*).

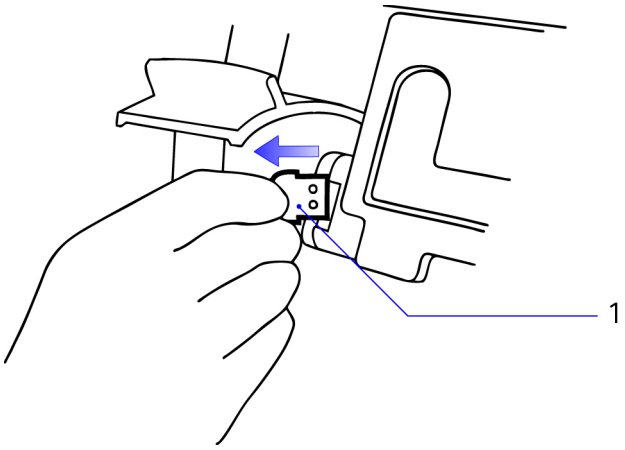
Figure 31: Probe Lever Positions



1. Closed Position
2. First Position
3. Second Position
4. Holding past the second position

4. Push the probe connector to the left and pull it out of the reagent inlet connector (*Figure 32*).

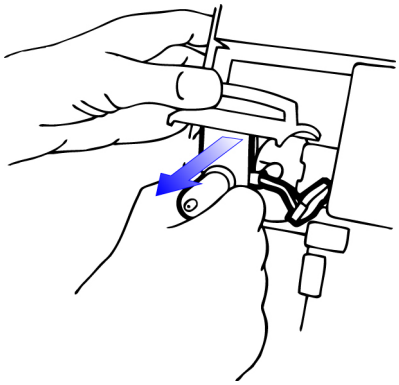
Figure 32: Disconnecting the Probe Connector



1.	Probe Connector

5. Lift the probe lever past the second position and hold in place (*Figure 31*).
6. Carefully hold the probe sleeve and pull firmly to remove the probe housing.
7. Release the probe lever and remove the probe housing (*Figure 33*).

Figure 33: Removing the Probe Housing

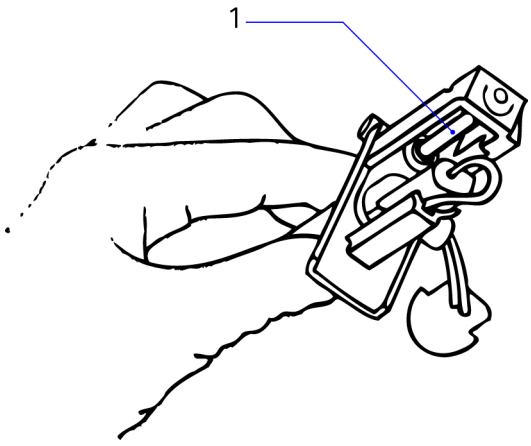


8. If you are replacing both the probe and the housing, lower the probe lever and go to *Replacing the Reference Sensor while Replacing Probe*, page 110, step 8. Otherwise, continue with the next step in the current procedure.
9. To clean the probe and housing, perform the following steps:
   a. Soak the assembly for 10 minutes in 10% v/v bleach.

b. Rinse with deionized water and gently dry with tissues.

c. Lightly grease the probe shaft mechanism (use the grease supplied with the pump tubing kit) (*Figure 34*).

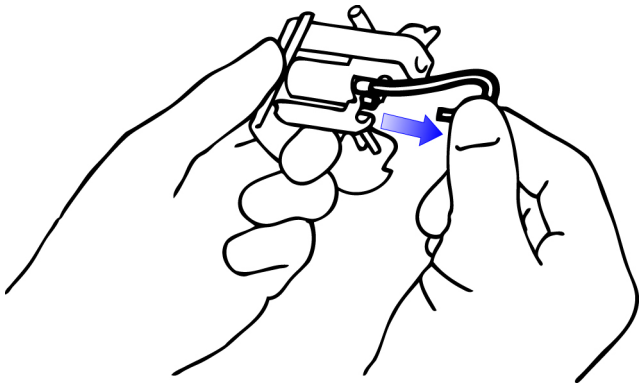
Figure 34: Greasing the Probe Shaft Mechanism



1.	Probe Shaft Mechanism

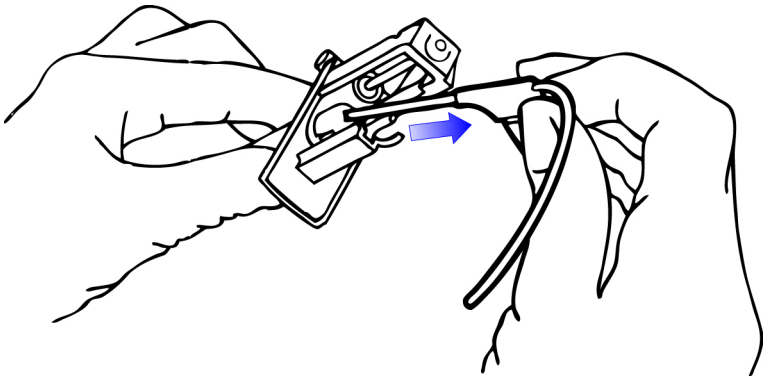
10. Disconnect the probe tubing from the housing (*Figure 35*).

Figure 35: Disconnecting the Probe Tubing from the Probe Housing.



11. Pull the probe out of the housing (*Figure 36*).

Figure 36: Removing the Probe from the Probe Housing



12. Discard the old part.

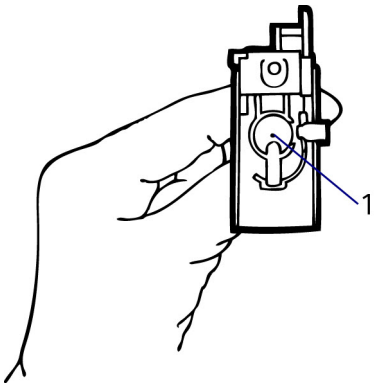
WARNING

Make sure the old probe is disposed of safely, in accordance with your laboratory guidelines.

Reassembling the Probe and Housing

1. Using replacement parts as required, feed the probe down through the hole in the probe sleeve, making sure it is seated correctly (*Figure 37*).

Figure 37: Probe Sleeve Hole

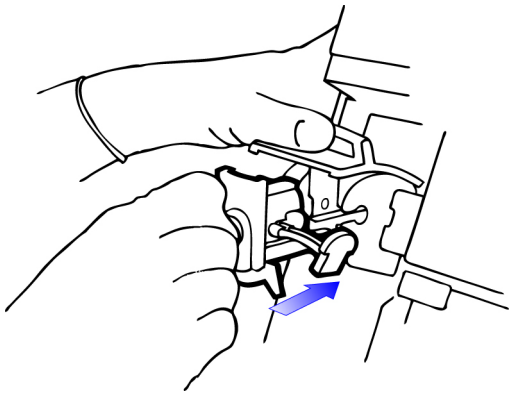


1. Probe Sleeve Hole

2. Connect the probe tubing to the housing.
3. Lift the probe lever past the second position and hold in place.
4. Hold the probe sleeve and slide the probe housing up the lever guides into position in the lever.

5. Release the probe lever (*Figure 38*).

Figure 38: Replacing the Probe Housing



6. If necessary, fit O-rings to the probe connector.
7. Slide the probe connector back into the reagent inlet connector.
8. Lower the probe lever.

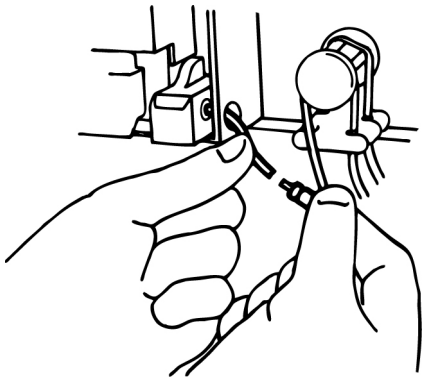
Replacing the Reference Sensor while Replacing Probe

1. Remove the reference sensor.

   See *Replacing the Reference Sensor Cassette or Inner Electrode,* page 97, steps 1–5.

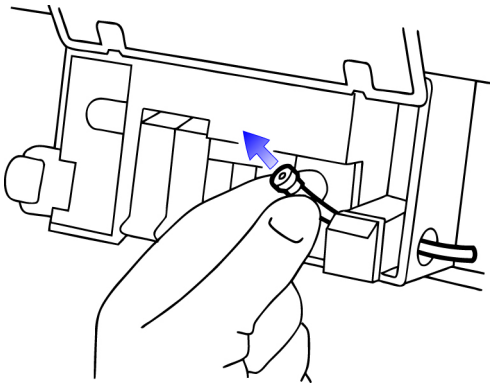
2. Disconnect the measurement block tube from the sample pump tubing. See *Figure 39*.

Figure 39: Disconnecting the Measurement Block Tube



3. Remove the measurement block tube and discard (*Figure 40*).

Figure 40: Removing the Measurement Block Tube



CAUTION

Take care when handling the measurement block tube as the residue from some protective gloves can adhere to the tube and therefore affect the fluid detector (FD2).

4. Fit the new measurement block tube and reconnect the sample pump tubing.
5. Replace the reference sensor, page 97, step 7.
6. Lower the front cover and restart the system.
7. To promote good flushing characteristics:
   a. Raise the probe lever to the first position.
   b. Immerse the tip of the probe in a small beaker of strong soap solution for 10 to 15 seconds.
   c. Lower the probe lever and Prime the system, page 85.

Replacing the Probe Protector

BIOHAZARD

See *Section 4, Safety Information*, for recommended precautions when working with biohazardous materials.

Equipment:

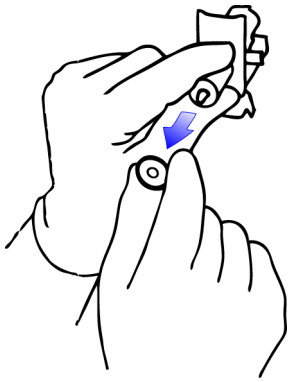
- Probe protector
- Probe and tubing kit
- Probe and housing kit

1. Remove the probe housing and probe. See page 106, steps 1–7.

   Do not discard the probe or housing.

2. Remove the probe protector from the probe housing (*Figure 41*).

Figure 41: Removing the Probe Protector



3. Fit a new probe protector.
4. Reassemble the probe and housing. See *Reassembling the Probe and Housing,* page 109.
5. Lower the front cover and restart the system.

Replacing the Pre-heater Tube

BIOHAZARD

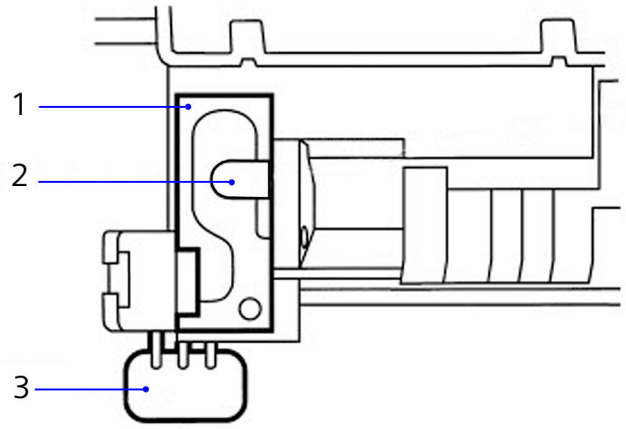
See *Section 4, Safety Information*, for recommended precautions when working with biohazardous materials.

Equipment:

- Pre-heater tube kit
- Phillips screwdriver
- Disinfectant

1. Use the Disinfect routine and then stop the system. See *Using the Disinfect Routine* and *Stopping the System,* page 84.
2. Remove the probe and probe housing. See Page *Removing the Current Probe, Tubing, and Housing,* page 106.
3. Remove the pO_2 and pCO_2 sensors. See *Refilling or Replacing the Measurement Sensors,* page 94.
4. Disconnect the reagent manifold connector (*Figure 42*).

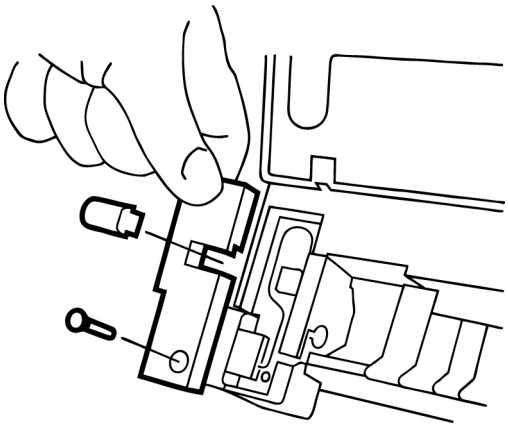
Figure 42: Pre-heater Components



1. Pre-heater Cover
2. Sample Detector Cover
3. Reagent Manifold Connector

5. Remove the sample detector cover.
6. Remove the screw from the pre-heater cover and remove the cover. See *Figure 43*.

Figure 43: Removing the Sample Detector Cover

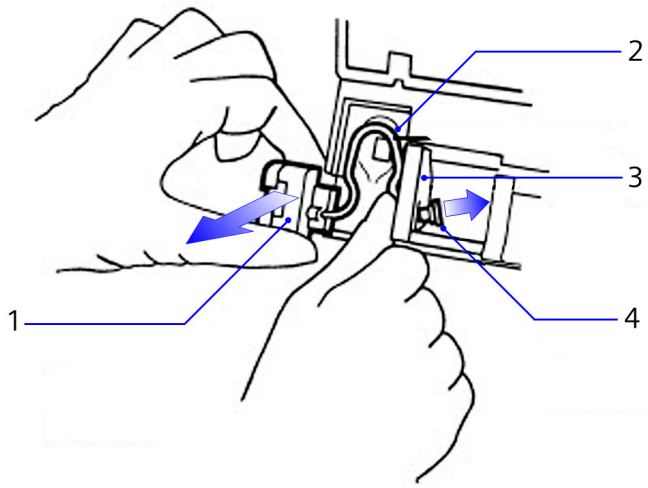


CAUTION

Handle the pre-heater tube carefully, as it is fragile and can easily be pinched.

7. Slide the reagent inlet connector towards you.
8. Ease the pre-heater tube from the groove in the pre-heater.
9. Carefully push the tube towards the measurement block to free the block connector (*Figure 44*).

Figure 44: Removing the Pre-heater Tube



1.	Reagent Inlet Connector
2.	Pre-heater Tube
3.	Plastic Moulding
4.	Block Connector

10. Ease the pre-heater tube under the plastic moulding.
11. Re-assemble using the new pre-heater tube assembly, making sure that the following conditions are met:
    - The pre-heater tube is in the pre-heater groove, and the block connector is in place.
    - The reagent inlet connector is in place.
    - The pre-heater cover and sample detector cover are replaced.
    - The reagent manifold connector is connected.
    - The pO_2 and pCO_2 sensors are replaced and seated correctly, and the block door is closed.
12. Replace the probe and probe housing. See *Replacing the Probe and Tubing and Probe Housing*, page 106.

13. Lower the front cover and restart the system.

Clearing Blockages

BIOHAZARD

See *Section 4, Safety Information*, for recommended precautions when working with biohazardous materials.

Always wear protective gloves when carrying out this procedure, and avoid spray contamination when clearing blockages with water.

Equipment:

- Clot removal line
- 1-mL syringe, as required

CAUTION

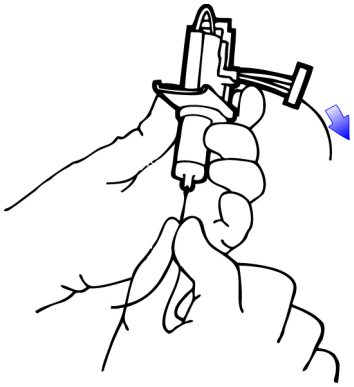
Use only Siemens clot removal line, as other materials might damage the system.

1. Stop the system, page 84.

Clearing a Blockage in the Probe

1. Remove the probe and housing. See *Replacing the Probe and Tubing and Probe Housing,* page 106.
2. Carefully thread the clot removal line up the probe until it appears through the probe connector, then pull the line through (*Figure 45*).

Figure 45: Clearing a Blockage in the Probe

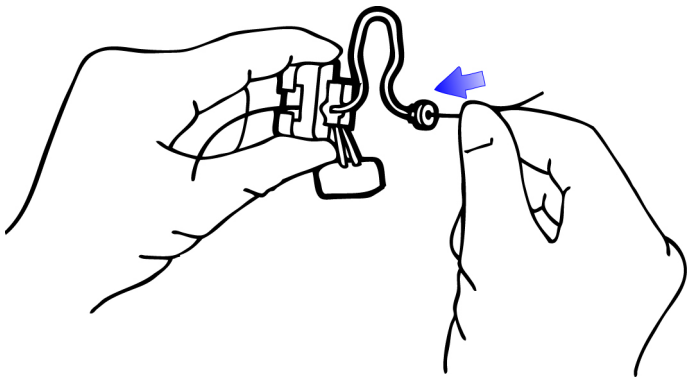


Clearing a Blockage in the Pre-heater

1. Remove the pre-heater tube assembly. See *Replacing the Pre-heater Tube,* page 112.

2. Pass the clot removal line through the pre-heater tube then pull the line through the reagent inlet connector (*Figure 46*).

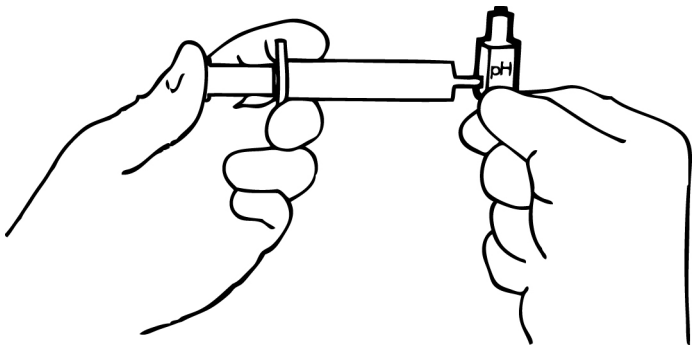
Figure 46: Clearing a Blockage in the Pre-Heater



Clearing a Blockage in the Sensors

1. Remove the sensors. See *Replacing the Reference Sensor Cassette or Inner Electrode*, page 97.
2. Use the syringe filled with deionized water to carefully inject water through the sensors but apply only very gentle pressure (*Figure 47*).

Figure 47: Clearing a Blockage in the Sensors



Clearing a Blockage in the Drip Tray Connector Drain Hole

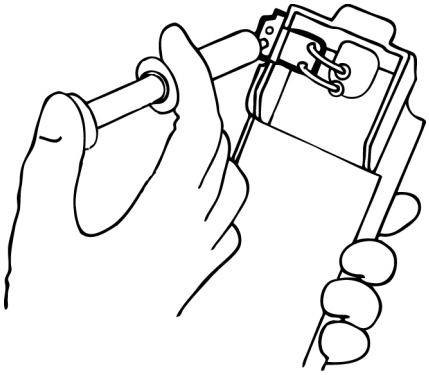
1. Remove the drip tray. See *Cleaning or Replacing the Drip Tray*, page 102.

2. Carefully inject water into the ports in the back of the drip tray connector (*Figure 48*).

WARNING

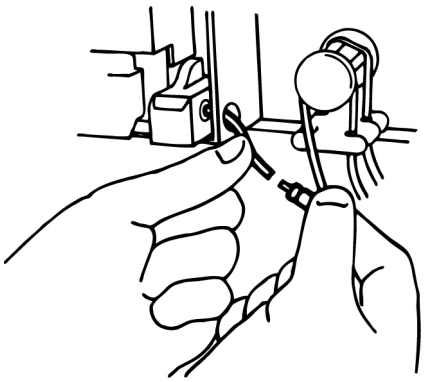
Point the drip tray away from you while you inject water into the ports.

Figure 48: Clearing a Blockage in the Drip Tray Connector Drain Hole



3. Disconnect the measurement block tube from the sample pump tubing connector (*Figure 49*).

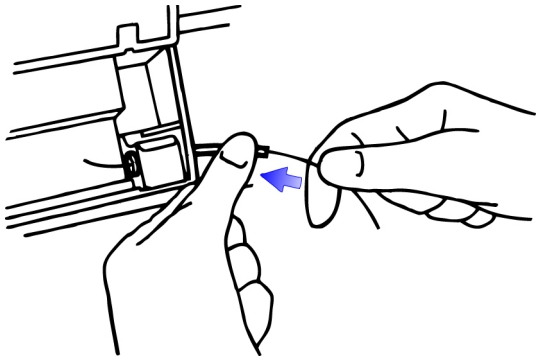
Figure 49: Disconnecting the Measurement Block Tube



4. Thread the clot removal line up the measurement block tube until it appears in the measurement block.

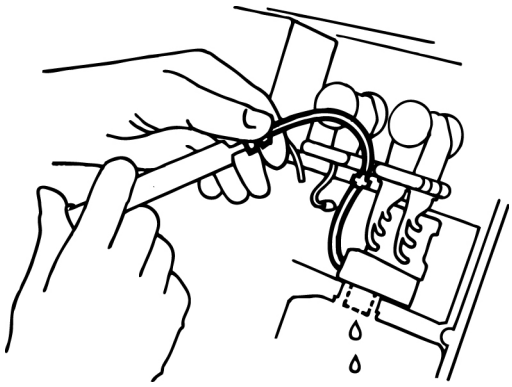
   Pull the line through (*Figure 50*).

Figure 50: Clearing a Blockage in the Measurement Block Tube



5. Carefully inject water into the sample pump tubing, until water appears at the waste cap (*Figure 51*).

Figure 51: Clearing a Blockage in the Sample Pump Tubing

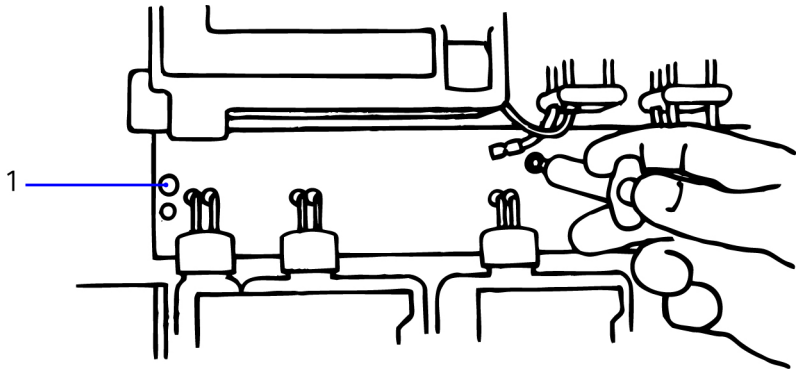


6. Reconnect the sample pump tubing to the measurement block tube.

Clearing a Blockage in the Manifold

1. Disconnect the waste tube from the manifold (*Figure 52*).

Figure 52: Clearing a Blockage in the Manifold



1. Drip Tray Drain Hole

2. Gently inject water into the waste tube port until it appears at the drip tray drain hole.
3. Hold tissues against the drain hole to catch the drips.
4. Re-assemble the system, restart the system and deproteinize the sensors, page 81.

Replacing Fuses

Equipment:

- Fuses: 250 V, T-1.25 A
- Flat-head screwdriver

WARNING

For continued protection against fire hazard, replace fuses only with the same type and rating of fuse that was originally in the system.

1. Contact your local technical provider or distributor to order replacement fuses.
2. Turn the system so that the back panel is facing you.

   The fuse holder is located in the back panel between the power cord and the power switch. It contains 2 fuses. Both fuses are required.
3. Turn the system off using the power switch.
4. Disconnect the power supply cord.

5. Locate the 2 grooves on the sides of the fuse holder.

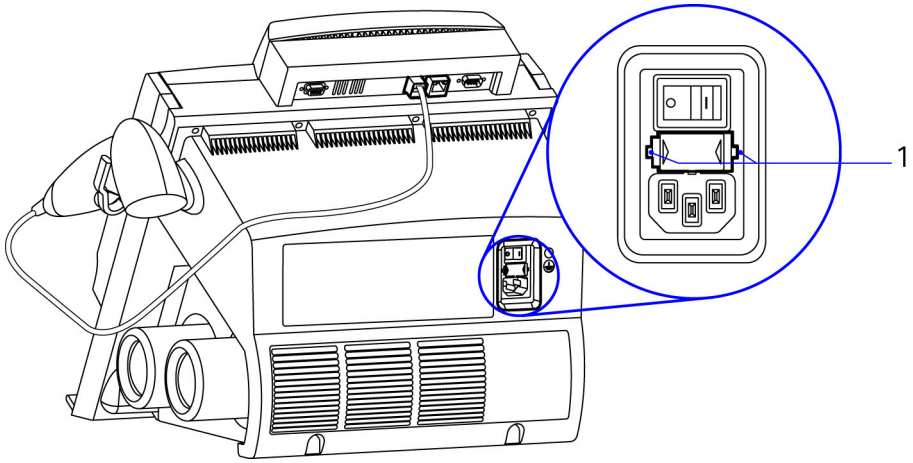
   The fuse cover has 2 grooves to the left and 2 grooves to the right of it.

CAUTION

Ensure you place the screwdriver blade in the smaller groove. You can damage the fuse block by placing the blade in the larger groove.

6. Insert the blade of a small flat-head screwdriver into the smallest groove on the left of the fuse holder.
7. Exert pressure to unsnap the left side of the fuse holder.

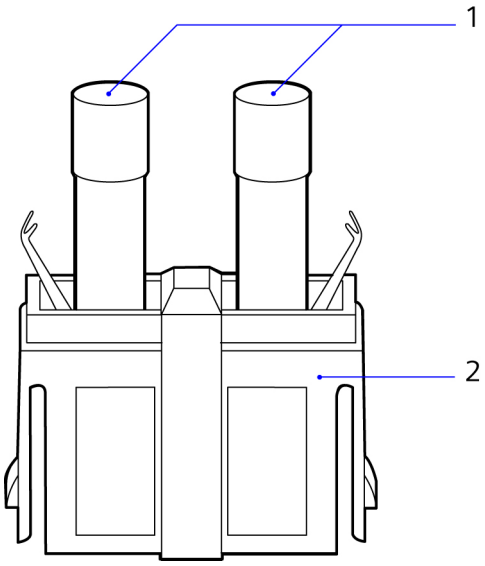
Figure 53: Opening the Fuse Cover



1. Small Grooves

8. Repeat steps 6–7 for the right groove.
9. Remove the fuse holder from the system.
10. Remove and dispose of the blown fuse or fuses (*Figure 54*).

Figure 54: Replacing Fuses



1. Fuse
2. Fuse Block

11. Insert the spare fuse onto the fuse block.
12. Insert the fuse holder securely into the system.
13. Reconnect the power supply cord.

Shutting Down the System

BIOHAZARD

See *Section 4, Safety Information*, for recommended precautions when working with biohazardous materials.

1. Wear gloves while carrying out the following procedures.

CAUTION

Siemens recommends that the system remain connected to the AC power supply at all times, so it is always ready for immediate use. When used as recommended will not require a warm-up period. However, if you must turn off the system, either by using the power switch or by disconnecting it from the AC supply, follow this shutdown procedure to prevent damage to the system.

Equipment:

- Disinfectant; bleach
- Tissues

1. Print the setup report and retain so that you have a record of all the settings. See *Printing the Setup Report,* page 171.
2. Use the Disinfect routine, *Using the Disinfect Routine,* page 83.
3. Disinfect the manifold and bottle tubing, and drain the system:

CAUTION

To prevent damaging the reference sensor if you use Virkon or 10% v/v bleach, you must remove the sensor and replace it with an old sensor, or a Test blank sensor - ref (TB5)

   a. Remove the buffer pack and wash bottle and replace with a beaker of disinfectant.

      Do not remove the waste bottle.

   b. Select **Ready > Settings > Maintenance > Prime**.
   c. When the Prime routine finishes, remove the disinfectant and replace with a beaker of deionized water.
   d. Select **Ready > Settings > Maintenance > Prime** again to flush the system with water.
   e. When the Prime routine finishes, remove the beaker of water.
   f. Place tissues under the bottle tubes to catch any drips.
   g. Select **Ready > Settings > Maintenance > Prime** again to drain the system.
   h. Remove the waste bottle and cap it.

4. Unscrew and remove the gas cartridges.
5. Power off the system using the power switch.
6. Disconnect the line cord from the power supply socket if necessary.
7. Remove the probe and housing and immerse in 10% v/v bleach for 10 minutes. See page 106.
8. Rinse the probe and housing with deionized water, then gently wipe dry.

   If necessary, grease the probe shaft lightly with the grease supplied with the pump tubing kit.

9. Remove the measurement sensors. See page 94.

10. Remove the reference sensor. See page 97.

    If you are removing the reference sensor from the system for more than 12 hours, follow this procedure to prevent damage to the Nafion inner electrode :

    a. Remove the inner electrode and store it in its container in saturated KCl.

CAUTION

Do not leave the inner electrode out of solution for longer than 10 minutes.

    b. Shake out the remaining KCl solution from the sensor cassette and rinse with deionized water.

    c. Flush the reference sensor sample path with deionized water, and allow the cassette to dry.

    d. To reactivate the reference sensor follow the procedure for installing a new sensor cassette.

11. Wipe the measurement block to remove any reference fill solution.

12. De-tension the pump tubes.

13. Clean the drip tray.

14. Wipe the external surfaces with tissues and 10% v/v bleach.

8 Troubleshooting

System Setup or Power Faults

The system continually performs self-diagnostic tests to maintain integrity of results. If the system detects a possible system setup fault, or if the system battery has failed or is failing, the system displays the Check Setup screen and resets the setup options to default values.

Note You can still use the system in this situation, but the data relating to the result is set to default (factory set) values.

1. Check the setup options in *Configuring Operating Setup,* page 164, and *Configuring System Setup,* page 168.
2. Check the barometer calibration setting, See *Calibrating the Barometer,* page 65.
3. When you have checked all the setup options, select **OK** to clear the Check Setup message and exit to the Ready screen.

General Troubleshooting Procedures

1. Ensure that the system is turned on and that all connections are secure.
2. Read the on-screen messages for indications of what is causing the problem.
3. Following a calibration, print the results and check the printout for further indications.
4. Consult the troubleshooting tables in this section.

System Not Ready

A Not Ready message indicates that the system is powered on but not yet ready for use.

1. Read the Not Ready message to determine what is causing the condition.

   If you have just powered on the system, the Not Ready message indicates that the system is warming up. See *What You Can Do during Warmup,* page 48.

2. If the Not Ready condition indicates that the system is in Standby mode, select **Standby > Restart** or **Standby > Select Auto Restart Time**.

3. If an error exists, follow the directions on the screen to clear the error condition.

4. If you have raised the probe, close the probe before proceeding.

Note If more than one error condition exists at startup, clearing the current error condition allows any lower-priority errors to display.

Calibration Failures

- *Calibration or Slope Drift,* page 128
- *Calibration or Slope No Endpoint,* page 131
- *Calibration or Slope Outside Range,* page 134
- *Fluidics Failure,* page 137

Viewing the Calibration Summary on the Screen

1. To view the troubleshooting indicators on the touch screen display, select **Ready > Settings > Troubleshooting > Sensors**.

   The same indicators appear on the display as on the printed summary.

2. Select the element you want to troubleshoot.

Calibration problems might also be caused by fluidics failures or by hydraulic problems. These conditions do not appear on the calibration summary. See the fluidics issues listed in the troubleshooting table in *Fluidics Failure,* page 137 for information. If hydraulic problems occur, contact your Siemens service representative.

Printing the Calibration Summary

1. To print the calibration summary to see possible further details of the problem, select **Ready > Settings > Data Recall > Print Cal Summary**.
2. Review the display or the printed calibration summary for the following indicators next to individual sensors:

Indicator	Calibration or slope condition
↑ or ↓	Drift
*****	No endpoint
!	Outside range

These same indicators appear on the Measuring Calibration screen. Select **Ready > Settings > Calibration**, then select the type of calibration you want to perform, next to the appropriate measurements.

Calibration or Slope Drift

Possible Cause	Action/Reference
New Sensor	
Instability in newly installed sensor.	Wait for sensor to stabilize. New sensors might take up to 90 minutes to stabilize. The system deselects a sensor if it fails calibration, but monitors the failed sensor and automatically reselects it when it meets calibration specifications.
Reference Sensor (pH/Electrolyte Drift)	
Bubble in reference sensor.	Debubble the sensor. *Replacing the Reference Sensor Cassette or Inner Electrode,* page 97.
Nafion inner electrode is dry due to a large bubble, or is not screwed down properly, or fits poorly.	Replace Nafion inner electrode if it is dry, or refit it correctly. *Replacing the Reference Sensor Cassette or Inner Electrode,* page 97.
Sensor is clogged with crystals caused by poor filling, or bubbles creating crystal growth. **Note** This applies only to the reference sensor.	Empty the sensor cassette and refill carefully with reference sensor fill solution. *Replacing the Reference Sensor Cassette or Inner Electrode,* page 97.
Vent hole is blocked.	Unblock the vent hole in the reservoir cap. *Clearing Blockages, page 115.*
Failed or leaking membrane.	Replace the sensor cassette. *Replacing the Reference Sensor Cassette or Inner Electrode,* page 97.
pH/Na^+/K^+/Ca^{++} or Cl^- Sensor	
Sensor needs deproteinizing and/or conditioning. **Note** Any sensor might require deproteinizing, but only the glass sensors (pH and Na^+ sensors) require conditioning.	• Deproteinize the sensor. *Deproteinizing the Sensors,* page 81. • Condition the sensor. *Conditioning the Sensors,* page 82.
Bubbles in fill solution, or insufficient or concentrated fill solution. The problem might also be caused by the reference sensor.	Debubble the sensor, or empty and refill. *Refilling or Replacing the Measurement Sensors,* page 94.

Possible Cause	Action/Reference
pCO_2/pO_2 Sensor	
Sensor needs deproteinizing.	Deproteinize the sensor. *Deproteinizing the Sensors,* page 81.
Sensor failure.	• Confirm failure by Measurement Block routine. *Measurement Block Routine,* page 144. • Replace the sensor. *Refilling or Replacing the Measurement Sensors,* page 94.
Hct Sensor	
Dampness around the sensor	• Dry off measurement block, contacts, and sensor. • Check sensor O-ring seal and replace if necessary. • Ensure that sensors are seated properly, and the tensioner is pushed firmly home. *Refilling or Replacing the Measurement Sensors,* page 94.
Insufficient reagent/wash delivery.	Ensure that the reagents/wash bottles contain sufficient solution. *Checking the Reagents,* page 79.
Bubbles in sensor or sample path.	• Ensure that the reagent pump tubing is tensioned. • Ensure that the measurement block tube is connected to the pump tubing. • Replace the pump tubing. *Changing the Pump Tubing,* page 89. • Check pre-heater assembly tubing. Replace pre-heater assembly. *Replacing the Pre-heater Tube,* page 112.
Poor measurement block washout, no or insufficient "pull" on sample line.	• Ensure that pump tubing is tensioned. • Ensure that measurement block tube is connected to the pump tubing. • Replace the pump tubing. *Changing the Pump Tubing,* page 89.
Sensor needs deproteinizing.	Deproteinize the sensor. *Deproteinizing the Sensors,* page 81.

Possible Cause	Action/Reference
Unsuccessful slope.	• Carry out calibration routine and slope, using a fresh slope ampule. • Repeat calibration routine and slope at least twice more, using a fresh slope ampule on each occasion.
Sensor failure.	• Confirm failure by Measurement Block routine. *Measurement Block Routine,* page 144. • Replace the sensor. *Refilling or Replacing the Measurement Sensors,* page 94.
System	
Dampness around the sensor.	• Dry off measurement block, contacts, and sensor. • Check sensor O-ring seal and replace if necessary. • Ensure that sensors are seated properly, and the tensioner is pushed firmly home. *Refilling or Replacing the Measurement Sensors,* page 94.
Partial blockage in sensors.	Clear the blockage. *Clearing Blockages,* page 115.
Gas cartridges connected incorrectly or gas flow rate incorrect.	• Ensure that cartridges are connected correctly and installed in correct position. *Changing the Gas Cartridges,* page 86. • Check gas flow rate. *Checking the Gas Flow Rate,* page 88.
Barometric pressure incorrect or changed.	Enter correct barometric pressure. *Calibrating the Barometer,* page 65.

Calibration or Slope No Endpoint

Possible Cause	Action/Reference
Reference Sensor (pH/Electrolyte Drift)	
Bubble in reference sensor.	Debubble the sensor. *Replacing the Reference Sensor Cassette or Inner Electrode,* page 97.
Nafion inner electrode is dry due to a large bubble, or is not screwed down properly, or fits poorly.	Replace Nafion inner electrode if dry, or refit it correctly. *Replacing the Reference Sensor Cassette or Inner Electrode,* page 97.
Sensor is clogged with crystals caused by poor filling, or bubbles creating crystal growth. **Note** This applies only to the reference sensor.	Empty the sensor cassette and refill carefully with reference sensor fill solution. *Replacing the Reference Sensor Cassette or Inner Electrode,* page 97.
Vent hole is blocked.	Unblock the vent hole in the reservoir cap. *Clearing Blockages,* page 115
Failed or leaking membrane.	Replace the sensor cassette. *Replacing the Reference Sensor Cassette or Inner Electrode,* page 97.
pH/Na^+/K^+/Ca^{++} or Cl^- Sensor	
Sensor needs deproteinizing and/or conditioning. **Note** Any sensor might require deproteinizing, but only the glass sensors (pH and Na^+ sensors) might require conditioning.	• Deproteinize the sensor. *Deproteinizing the Sensors,* page 81. • Condition the sensor. *Conditioning the Sensors,* page 82.
Bubbles in fill solution, or insufficient or concentrated fill solution. The problem might also be caused by the reference sensor.	Debubble the sensor, or empty and refill. *Refilling or Replacing the Measurement Sensors,* page 94.
***p*CO_2/*p*O_2 Sensor**	
Sensor needs deproteinizing.	Deproteinize the sensor. *Deproteinizing the Sensors,* page 81.

Possible Cause	Action/Reference
Sensor failure.	• Confirm failure by Measurement Block routine. *Measurement Block Routine,* page 144. • Replace the sensor. *Refilling or Replacing the Measurement Sensors,* page 94.
Hct Sensor	
Note The Hct sensor has no active layers/membranes, therefore it is very reliable. Check for the following problems and carry out the actions shown. If these are unsuccessful, replace the sensor.	
Dampness around the sensor	• Dry off measurement block, contacts, and sensor. • Check sensor O-ring seal and replace if necessary. • Ensure that sensors are seated properly, and the tensioner is pushed firmly home. *Refilling or Replacing the Measurement Sensors,* page 94.
Insufficient reagent/wash delivery.	Ensure that the reagents/wash bottles contain sufficient solution. *Checking the Reagents,* page 79.
Bubbles in sensor or sample path.	• Ensure that the reagent pump tubing is tensioned. • Ensure that the measurement block tube is connected to the pump tubing. • Replace the pump tubing. *Changing the Pump Tubing,* page 89. • Check pre-heater assembly tubing. Replace pre-heater assembly. *Replacing the Pre-heater Tube,* page 112.
Poor measurement block washout, no or insufficient "pull" on sample line.	• Ensure that pump tubing is tensioned. • Ensure that measurement block tube is connected to the pump tubing. • Replace the pump tubing. *Changing the Pump Tubing,* page 89.
Sensor needs deproteinizing.	Deproteinize the sensor. *Deproteinizing the Sensors,* page 81.

Possible Cause	Action/Reference
Unsuccessful slope.	• Carry out calibration routine and slope, using a fresh slope ampule. • Repeat calibration routine and slope at least twice more, using a fresh slope ampule on each occasion.
Sensor failure.	• Confirm failure by Measurement Block routine. *Measurement Block Routine,* page 144. • Replace the sensor. *Refilling or Replacing the Measurement Sensors,* page 94.
System	
Dampness around the sensor.	• Dry off measurement block, contacts, and sensor. • Check sensor O-ring seal and replace if necessary. • Ensure that sensors are seated properly, and the tensioner is pushed firmly home. *Refilling or Replacing the Measurement Sensors,* page 94.
Partial blockage in sensors.	Clear the blockage. *Clearing Blockages,* page 115.
Gas cartridges connected incorrectly or gas flow rate incorrect.	• Ensure that cartridges are connected correctly and installed in correct position. *Changing the Gas Cartridges,* page 86. • Check gas flow rate. *Checking the Gas Flow Rate,* page 88.
Bubble in sample path - specifically under the reference sensor.	• Repeat the measurement. • Watch the solution being aspirated to determine the cause of the bubble.
Very occasionally, worn pump tubing may cause instability on one or more channels.	Replace the pump tubing. *Changing the Pump Tubing,* page 89.
Very occasionally, dampness around the pre-heater, or at the insulating bushes at either end of the sample path may cause instability.	Carefully clean and dry the affected areas.

Calibration or Slope Outside Range

Possible Cause	Action/Reference
Reference Sensor (pH/Electrolyte Drift)	
Bubble in the reference sensor.	Debubble the sensor. *Replacing the Reference Sensor Cassette or Inner Electrode,* page 97.
Nafion inner electrode is dry due to a large bubble, or is not screwed down properly, or fits poorly.	Replace Nafion inner electrode if dry, or refit it correctly. *Replacing the Reference Sensor Cassette or Inner Electrode,* page 97.
Sensor is clogged with crystals caused by poor filling, or bubbles creating crystal growth. **Note** This applies only to the reference sensor.	Empty the sensor cassette and refill carefully with reference sensor fill solution. *Replacing the Reference Sensor Cassette or Inner Electrode,* page 97.
Vent hole is blocked.	Unblock the vent hole in the reservoir cap. *Clearing Blockages,* page 115.
Failed or leaking membrane.	Replace the sensor cassette. *Replacing the Reference Sensor Cassette or Inner Electrode,* page 97.
pH/Na^+/K^+/Ca^{++} or Cl^- Sensor	
Sensors fitted incorrectly.	Verify that sensors are in the correct position.
Bubbles in fill solution, or insufficient or concentrated fill solution. The problem might also be caused by the reference sensor.	Debubble the sensor, or empty and refill. *Refilling or Replacing the Measurement Sensors,* page 94.
Sensor failure.	• Confirm failure by Measurement Block routine. *Measurement Block Routine,* page 144. • Replace the sensor. *Refilling or Replacing the Measurement Sensors,* page 94.
Sensor needs conditioning (pH and Na^+ sensors only).	Condition the sensor. *Conditioning the Sensors,* page 82.
Sensor needs deproteinizing.	Deproteinize the sensor. *Deproteinizing the Sensors,* page 81.

Possible Cause	Action/Reference
pCO_2 /pO_2 Sensor	
Sensor needs deproteinizing.	Deproteinize the sensor. *Deproteinizing the Sensors,* page 81.
Sensor failure.	• Confirm failure by Measurement Block routine. *Measurement Block Routine,* page 144. • Replace the sensor. *Refilling or Replacing the Measurement Sensors,* page 94.
Hct Sensor	
Note The Hct sensor has no active layers/membranes, therefore it is very reliable. Check for the following problems and carry out the actions shown. If these are unsuccessful, replace the sensor.	
Dampness around the sensor	• Dry off measurement block, contacts, and sensor. • Check sensor O-ring seal and replace if necessary. • Ensure that sensors are seated properly, and the tensioner is pushed firmly home. *Refilling or Replacing the Measurement Sensors,* page 94.
Insufficient reagent/wash delivery.	Ensure that the reagents/wash bottles contain sufficient solution. *Checking the Reagents,* page 79.
Bubbles in sensor or sample path.	• Ensure that the reagent pump tubing is tensioned. • Ensure that the measurement block tube is connected to the pump tubing. • Replace the pump tubing. *Changing the Pump Tubing,* page 89. • Check pre-heater assembly tubing. Replace pre-heater assembly. *Replacing the Pre-heater Tube,* page 112.

Possible Cause	Action/Reference
Poor measurement block washout, no or insufficient "pull" on sample line.	• Ensure that pump tubing is tensioned. • Ensure that measurement block tube is connected to the pump tubing. • Replace the pump tubing. *Changing the Pump Tubing,* page 89.
Sensor needs deproteinizing.	Deproteinize the sensor. *Deproteinizing the Sensors,* page 81.
Unsuccessful slope.	• Carry out calibration routine and slope using a fresh slope ampule. • Repeat calibration routine and slope at least twice more, using a fresh slope ampule on each occasion.
Sensor failure.	• Confirm the failure by using the Measurement Block routine. *Measurement Block Routine,* page 144. • Replace the sensor. *Refilling or Replacing the Measurement Sensors,* page 94.
System	
Dampness around the sensor –OR– Measurement block assembly and sensors are wet.	• Dry off measurement block, contacts, and sensor. • Check sensor O-ring seal and replace if necessary. • Ensure that sensors are seated properly, and the tensioner is pushed firmly home. *Refilling or Replacing the Measurement Sensors,* page 94.
Worn pump tubing.	Replace the pump tubing. *Changing the Pump Tubing,* page 89.
Gas cartridges are connected incorrectly or gas flow rate is incorrect.	• Ensure that cartridges are connected correctly and installed in correct position. *Changing the Gas Cartridges,* page 86. • Check gas flow rate. *Checking the Gas Flow Rate,* page 88

Fluidics Failure

Possible Cause	Action/Reference
Reagents	
Buffer or wash bottles are empty.	Replace buffers or wash bottles. *Emptying the Waste Bottle*, page 78 also describes how to handle and reuse the empty wash bottle.
Bottle tubes do not reach the solution.	Feed the tubes through the connector caps into the solutions. *Checking the Reagents*, page 79.
System	
Blockage in the sample path.	Clear the blockage. *Clearing Blockages*, page 115.
Leaks in sample path.	• Fix all leaks. • Check sensor O-ring seals and make sure sensors are seated correctly and the sensor tensioner is pushed firmly home. Check probe connector O-rings and replace if necessary. *Refilling or Replacing the Measurement Sensors*, page 94. *Replacing the Reference Sensor Cassette or Inner Electrode*, page 97 . *Replacing the Probe and Tubing and Probe Housing*, page 106.
Aspirating air on calibrant or sample line.	Fix the leak.
New/greasy probe.	1. Raise probe lever and immerse tip of probe in a strong soap solution for 10 to 15 seconds. 2. Lower the probe lever and prime the system. *Using the Prime Routine*, page 85.
Damaged seal in probe sleeve caused by bent probe	Replace probe and housing. *Replacing the Probe and Tubing and Probe Housing*, page 106.

Possible Cause	Action/Reference
Pump Tubing	
Insufficient "pull" on calibrant line.	1. Check that the reagent pump tubing is tensioned. 2. Check that the rubber connector is pushed firmly onto manifold. 3. Replace the tubing. *Changing the Pump Tubing,* page 89.
Tubing is blocked.	• Clear the blockage. *Clearing Blockages,* page 115. • If fault persists replace the tubing. *Changing the Pump Tubing,* page 89.
Mechanical	
Pump rollers are dirty.	Remove pump rollers, clean, grease and re-assemble. *Cleaning the Rollers,* page 91.
Probe is misaligned.	Realign or replace probe. *Replacing the Probe and Tubing and Probe Housing,* page 106.
Solenoid(s) inoperative.	Contact your local technical provider or distributor. See *Appendix B, Warranty and Support Information*.
Fluid Detector	
Sample detector cover not fitted.	• Fit the cover properly. *Replacing the Pre-heater Tube,* page 112.
Ambient light affecting fluid detector.	• Position system out of direct sunlight.
Dirty tubing.	• Replace probe tubing and measurement block tube. *Changing the Pump Tubing,* page 89.
Detector failure.	• Confirm failure using the Sample Flow routine, page 148. • Replace detector. See replacement instructions on the detector packaging.

Suspect Patient Results

Note Suspect results: Results that in your professional judgment seem unlikely. These can be caused by a poorly maintained reference sensor (for example, protein build up on the reference sensor membrane), bubbles in the fill solution, or crystal growth. Under these conditions aqueous solutions (for example, QC material) diffuse across the reference sensor membrane at a different rate from non-aqueous solutions (for example, patient samples), and therefore QC results might not be affected.

General Procedure When Suspect Patient Results Occur

If the system reports patient results that seem suspect, perform the following procedures:

1. Deproteinize the sample path.
2. Debubble the reference sensor and remove the bubbles.
3. Remove any crystals in the reference sensor.
4. Empty the sensor cassette.
5. Refill carefully with reference sensor fill solution.
6. If the problem still exists, replace the reference sensor cassette.

   See *Replacing the Reference Sensor Cassette or Inner Electrode*, page 97.

Suspect Results, Possible Causes and Corrective Actions

Possible Cause	Action/Reference
Reference Sensor	
Bubble in the reference sensor.	Debubble the sensor. *Replacing the Reference Sensor Cassette or Inner Electrode*, page 97.
Crystals in the bottom of the reference sensor. **Note** Crystal growth occurs only in the reference sensor.	1. Remove any crystals in the reference sensor. 2. Empty the sensor cassette. 3. Refill carefully with reference sensor fill solution. 4. If the problem still exists, replace the reference sensor cassette. *Replacing the Reference Sensor Cassette or Inner Electrode*, page 97.
Possible Cause	**Action/Reference**
Failed or leaking membrane.	Replace the reference sensor cassette. *Replacing the Reference Sensor Cassette or Inner Electrode*, page 97.
System	
Ca^{++} or Cl^{-} sensor installed, incorrect sensor selected.	Select correct measured parameters. *Selecting Measurement Parameters*, page 169.
Correlation factors changed.	Reset to the correct factors *Adjusting Correlation*, page 166.
Calibrants used for longer than 21 days.	Replace the Buffer Pack *Checking the Reagents*, page 79.
Sample creep caused by a blockage (for example, a fibrin clot in the sample path).	Clear the blockage *Clearing Blockages*, page 115.
Bubbles in the sensor fill solution.	Debubble the sensors. *Deproteinizing the Sensors, page 81*.
Sample	
Sample improperly collected or stored.	• Obtain a fresh sample. • Analyze sample as soon as possible after collection. See *Handling and Storing Samples*, page 34. • Store unused sample properly.

Possible Cause	Action/Reference
QC	
Problem could be caused by: • abnormal pH • interfering ions • wrong matrix • wrong assigned values • use of other aqueous standards • improper handling	• Use only recommended QC materials. • Handle QC materials properly. *Handling QC Samples,* page 69. • Verify that the settings and solutions you are using are correct. • If the problem is interfering ions, run the deproteinizing routine. *Deproteinizing the Sensors,* page 81.
Note If you encounter any of these issues while using Siemens QC samples, make sure that the operating and system settings are correct. If a QC sample results are within the measurement range, you should not encounter a problem with an abnormal pH.	
Capillary Samples	
Small bubbles that are not detected.	Take care when aspirating capillary samples.
No sample in measurement block • Sample not detected, or sampling fault (system) • Fluid detector issues	• Reposition sample. • Repeat sample measurement.
False “sampling complete” or “micro sample” indications. Segments of Wash solution in sample path causing false 'sampling complete' or 'micro sample' indications • Sample not detected, or sampling fault	Clear blockages in drip tray/manifold/pump tubing. *Clearing Blockages,* page 115.

Sample Not Detected or Sampling Faults

Possible Cause	Action/Reference
Pump Tubing	
No or insufficient “pull” on the sample line.	1. Verify that the pump tubing is tensioned. 2. Verify that the measurement block tube is connected to the pump tubing. 3. Replace the pump tubing. *Changing the Pump Tubing and Cleaning and Lubricating the Rollers,* page 89.

Possible Cause	Action/Reference
System	
No sample in the measurement block.	Repeat the sample measurement.
Blockage in the sample path.	Clear the blockage. *Clearing Blockages*, page 115.
Segments of wash solution in the sample path are causing false sampling complete or micro sample indications.	• Check for blockages in the drip tray, manifold, or pump tubing. • Clear any existing blockage. *Clearing Blockages*, page 115.
Leaks in the sample path.	• Fix all leaks. • Check sensor O-ring seals. • Make sure sensors are seated correctly and the sensor tensioner is pushed firmly home. • Check the probe connector O-rings and replace if necessary. *Refilling or Replacing the Measurement Sensors*, page 94. *Replacing the Reference Sensor Cassette or Inner Electrode*, page 97 . *Replacing the Probe and Tubing and Probe Housing*, page 106.
Aspirating air on the sample line.	Fix the leak.
Fluid Detector	
Sample detector cover not fitted.	Fit the cover properly. *Replacing the Pre-heater Tube*, page 112.
Ambient light affecting fluid detector.	Position system out of direct sunlight.
Dirty tubing.	Replace the probe tubing and the measurement block tube. *Replacing the Probe and Tubing and Probe Housing*, page 106. *Changing the Pump Tubing*, page 89.
Detector failure.	• Confirm failure by using the Sample Flow routine, page 148. • Replace the failed detector. See replacement instructions on detector packaging.

Printer Issues

Possible Cause	Action/Reference
No printout	
Printer is turned off or options not selected.	Verify that the printer is turned on and the appropriate options are selected in **Ready > Settings > Operating Setup > Printer Options**.
Paper loaded incorrectly.	Load paper correctly. *Replacing the Printer Paper,* page 104.
Printer failure.	• Confirm failure by running the Roll Printer routine. *Roll Printer Routine,* page 150. • Contact your local technical provider or distributor. See *Appendix B, Warranty and Support Information*.
Paper jammed.	Fix paper jam. *Replacing the Printer Paper,* page 104**.**

Heater Failure

If the display shows Heater Failed, the system does not allow calibrations or sample measurements. Perform the following procedures:

1. Use the Heater routine, page 149, to determine which heater has failed.

   The system has 2 heater systems: a Sensor Block Heater to maintain the sensor block at 37°C, and a Pre-heater to preheat samples and reagents to 37°C.

2. Contact your local technical provider or distributor.

Using the Troubleshooting Routines

1. Select **Ready > Settings > Troubleshooting**.
2. Select the troubleshooting routine that you want to perform.

Measurement Block Routine

The Measurement Block routine measures and displays the sensor output in mV or pA. By comparing the readings to the values given, you can see if the sensors require maintenance, or if they should be replaced. You can also use this routine (running 7.3 or 6.8 buffer) to help diagnose fluidics failures.

Note Channels that have been auto deselected are still measured and displayed in this routine.

1. Select **Ready > Settings > Troubleshooting > Measurement Block**.
2. Select the buffer or gas test you want to run.

   The system displays the measurement in mV/pA.

3. Compare the mV/pA readings with these values[1] :

pH	**7.3 Buffer pH (mV)**	**6.8 Buffer pH (mV)**
Nominal mV	+300.0	+330.0
Total pull in range	194.0 to 406.0	23.1 to 38.0 above 7.3 buffer mV value
Action limits	< 270.0 or > 330.0	< 27 or > 35 above
Na^+	**7.3 Buffer Na^+ (mV)**	**6.8 Buffer Na^+ (mV)**
Nominal mV	+80.0	+74.0
Total pull in range	29.0 to 126.0	-4.4 to -7.2 below 7.3 buffer mV value
Action limits	< 50.0 or > 90.0	< 4.8 or > 6.8 below 7.3 buffer mV value
K^+	**7.3 Buffer K^+ (mV)**	**6.8 Buffer K^+ (mV)**
Nominal mV	+80.0	+97.0
Total pull in range	29.0 to 126.0	12.8 to 21.0 above 7.3 buffer mV value
Action limits	< 50.0 or > 90.0	< 16.0 or > 19.5 above 7.3 buffer mV value
Ca^{++}	**7.3 Buffer Ca^{++}**	**6.8 Buffer Ca^{++} (mV)**
Nominal mV	+80.0	+89.3
Total pull in range	29.0 to 126.0	5.7 to 11.1 above 7.3 buffer mV value
Action limits	< 55.0 or > 105.0	< 6.6 or > 10.2 above 7.3 buffer mV value
Cl^-	**7.3 Buffer Cl^- (mV)**	**6.8 Buffer Cl^- (mV)**
Nominal mV	+80.0	+89.5
Total pull in range	29.0 to 126.0	6.6 to 10.6 above 7.3 buffer mV value
Action limits	< 70.0 or > 110.0	< 8.0 or > 9.5 above 7.3 buffer mV value
Hct	**7.3 Buffer Hct (mV)**	**Hct Slope (mV)**
Nominal mV	+3.50	+6.15
Total pull in range	-1.05 to 7.35	4.96 to 7.07 above 7.3 buffer mV value
pCO_2	**Cal Gas pCO_2 (mV)**	**Slope Gas pCO_2 (mV)**
Nominal mV	-170.0	-151.0

1. at 760 mmHg atmospheric pressure.

Total pull in range	-300.0 to +100.0	12.8 to 20.6 above cal gas mV value
Action limits	< -270.0 or > +80.0	< 13.5 or > 20.2 above cal gas mV value
pO_2	**Cal Gas pO_2, (pA)**	**Slope Gas pO_2, (pA)**
Nominal pA	+764.0	+10.0
Total pull in range	171 to 1711 above slope gas pA value	-100.0 to +200.0
Action limits	< 300 or > 1400 above slope gas pA value	< -50 or > 150
Action	pH/Na^+/K^+/Ca^{++}/Cl^-: this might be caused by the reference sensor, see page 97 and following. If problems persist, deproteinize, condition or refill the sensor. If the problem is still apparent, replace the sensor. See *Deproteinizing the Sensors,* page 81 or *Replacing the Reference Sensor Cassette or Inner Electrode,* page 97. pCO_2/pO_2: Replace the sensor. See *Replacing the Reference Sensor Cassette or Inner Electrode,* page 97.	

Stability: For 7.3 Buffer and Cal Gas, a typical sensor shows the following performance:

	pH	**Na^+**	**K^+**
Noise: After 15 seconds, the display does not change by more than the values shown in this row.	0.12 mV/10 sec	0.18 mV/10 sec	0.13 mV/10 sec
Drift: After 15 seconds the display does not change unidirectionally by more than this value during the remainder of the measurement.	0.13 mV	0.18 mV	0.13 mV

	Ca^{++}	Cl^{-}	Hct
Noise: After 15 seconds the display does not change by more than the values shown in this row.	0.1 mV/10 sec	0.25 mV/10 sec	00.95 mV/10 sec
Drift: After 15 seconds the display does not change unidirectionally by more than this value during the remainder of the measurement.	0.1 mV	0.25 mV	0.05 mV

	pCO_2	pO_2
Noise: After 15 seconds the display does not change by more than the values shown in this row.	0.14 mV/10 sec	1.1 pA/10 sec
Drift: After 15 seconds the display does not change unidirectionally by more than this value during the remainder of the measurement.	0.14 mV	3.4 pA

Instability on the pH/Na^{+}/K^{+}/Ca^{++}/Cl^{-} channel might be caused by the reference sensor. De-bubble the reference sensor and repeat the test.

4. Select **Cancel** to cancel the test.

   Note If the error message: pO_2 offset cal required is printed, contact your local technical provider or distributor.

Run Test Sample

Use the Run Test Sample routine to:

- Measure a sample with a known mV value (for example, run 7.3 or 6.8 buffer as a sample).
- Run Hct slope.

Note You cannot use capillary samples with the Run Test Sample routine.

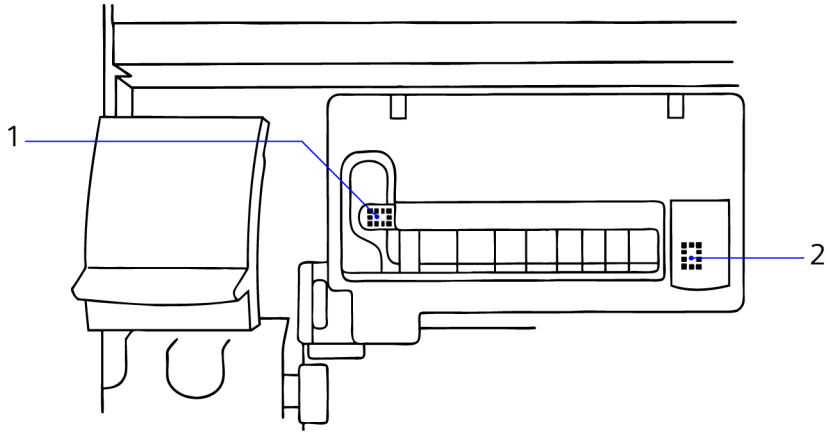
Sample Flow Routine

The Sample Flow routine checks the sample pathway from probe to waste bottle. It also checks the fluid detectors.

1. Select **Ready** (or **Not Ready**) **> Settings > Troubleshooting > Sample Flow**.
2. Lift the probe to test sample flow.
3. Present a test sample (for example, a QC sample).
4. To start the sampling, select **Start**.
5. Watch the sample as it goes through the pre-heater.
6. When the sample reaches the first fluid detector, verify that the FD1 box on the display changes from white to black (*Figure 55*).

   If the system detects no fluid, the boxes remain white.

Figure 55: Location of Fluid Detectors



1. Fluid Detector 1 (FD1)
2. Fluid Detector 2 (FD2)

7. Watch the sample as it goes through the measurement block.
8. When the sample reaches the second fluid detector, verify that the FD2 box on the display changes from white to black.
9. After the sample reaches the detectors, remove the sample from the probe.
10. Watch the trailing edge of the sample as it goes through the pre-heater.
11. When the trailing edge of the sample reaches the first fluid detector, verify that the FD1 box on the display changes from black to white.
12. Watch the trailing edge as it goes through the measurement block.
13. When the trailing edge reaches the second fluid detector, verify that the FD2 box on the display changes from black to white.
14. To repeat the test, present the sample again and remove it.
15. Close the probe to cancel the test.
16. If either of the fluid detectors fails the test, replace it according to the instructions on the packaging.

    Note After 1 minute of system inactivity, the system beeps twice every few seconds until you close the probe.
17. If no sample is in the measurement block at the time of the test, you might see a fluid detector issue:
    a. Reposition the sample.
    b. Repeat the sample measurement.

Heater Routine

The Heater routine displays the system temperature, the temperature of the pre-heater and the temperature of the sensors.

1. Select **Ready** (or **Not Ready**) **> Settings > Troubleshooting > Heater**.

   If the temperature is outside specification, the system displays Warming up or Heater failed.
2. If Warming up is constantly displayed, or if Heater failed is displayed, contact your local technical provider or distributor.

Electronics Routine

The Electronics routine checks the system's electronic functions:

- Electronics 1 (system RAM tests)

- Electronics 2 (ADC, voltage reference buffer, voltage offset DAC, motor DAC, comparitor port)
- Electronics 3 (display RAM) Heater
- BP sensor
- Probe
- Real time clock
- Fluid detectors

To run the Electronics routine, perform the following steps:

1. Select **Ready** (or **Not Ready**) **> Settings > Troubleshooting > Electronics**.
   - When the system completes this routine, it confirms that the testing was successful.
   - If a test fails three attempts, the system displays the test name and a failed message.
2. Contact your local technical provider or distributor if any electronics test fails.

Roll Printer Routine

The Roll Printer routine checks the internal printer.

1. Select **Ready** (or **Not Ready**) **> Settings > Troubleshooting > Roll Printer**.

   The printer prints the following test set:

   ```
   1234567890123456789012345678901 2
   3456789012345678901234567890123 4
   5678901234567890123456789012345 6
   7890123456789012345678901234567 8
   9012345678901234567890123456789 0

   --------------------------------
   ```

2. If the system does not print the test set, verify that the printer is on, that you have loaded the paper correctly and that the paper is not jammed. See page 104.
3. If the system still does not print, contact your local technical provider or distributor.

Sensors Routine

The Sensors routine reports up to 4 calibration faults, in the following priority:

Sensors: pH
pCO_2
pO_2
Na^+
K^+
Ca^{++}
Cl^-
Hct

Faults: no endpoint, drift, outside range

1. Select **Ready** (or **Not Ready**) **> Settings > Troubleshooting**> **Sensors**.

   Follow the appropriate troubleshooting routines. See page 125 and following.

Other Problems

Indicator	Possible Cause
Maintenance or QC prompts do not appear	• Prompts are not set. See *Setting the Maintenance Prompts,* page 168 and *QC Prompts Setup,* page 164.
No data shown for measured parameters, on display or printout	• Parameter is not selected. See *Selecting Measurement Parameters,* page 169. • Parameter is selected, but has failed calibration, and is not available for sample/QC measurement.
No data shown for calculated parameters, on display or printout	• The display shows a maximum of 8 parameters, but all selected parameters are printed. • Parameter is not selected. See *Selecting Calculated Parameters,* page 169 • Parameter is selected, but appropriate measurement channels are not selected, or are not available; or *c*tHb and F_IO_2 are not available.
Automatic micro sample mode not available	Insufficient sample (minimum 50 µL).

Indicator	Possible Cause
Hct Slope Overdue is printed	Hct slope prompt has been displayed for more than 24 hours.
QC Overdue is printed	More than one QC prompt has become due.
Beeper sounds during data entry	• Entry field is full, and number key pressed. • Entry field is empty and Cancel key pressed. • Data entered is invalid.
Beeper sounds during sample or QC data recall	• At start of records and you select **Back**. • At end of records and you select **Next**.
Atmospheric pressure cannot be changed	• Entered value differs from the displayed value by more than ±20 mmHg. • BP sensor is faulty. Contact your local technical provider or distributor.

9 Data Management

Managing Sample Data

The system retains the data for the last 250 samples measured. Using the Data Recall menu, you can perform the following functions:

- Recall data for each of the last 250 samples.
- Enter or change patient data for each recalled sample.
- Print the results for each recalled sample.

See *Recalling Sample Data,* page 60 for a detailed process description.

Managing QC Data

The system retains the data for the last 90 QC samples measured for each QC level.

Statistics are calculated for Levels 1–3, and Hct Level A and B. Level X has no statistical data for Level X, because it has no range checking.

Use the Data Recall menu to perform the following functions:

- Print statistical data for Levels 1–3 and Hct Levels A and B.
- Recall data for each QC sample.
- Reassign QC data to another level.
- Print results for each QC sample to be printed.

See *Recalling and Printing QC Data,* page 71 for a detailed process description.

Managing Calibration Summary Data

The system maintains a calibration summary for all calibrations within a 24-hour period.

If you select Cal Summary (see *Setting Printer Options,* page 166), the system automatically prints the summary every day at the end of the first calibration after 6 A.M.

Use the Data Recall menu to manually initiate a calibration summary printout. See *Recalling and Printing Calibration Data,* page 66 for a detailed process description.

10 System Installation and Configuration

You can use the system with the default (factory set) options and values, but there are several setup options available that let you customize the system for your laboratory. Where applicable, we have recommended settings.

Installation

Your system should be installed by an authorized Siemens representative.

CAUTION
The electromagnetic environment should be evaluated prior to operation of the device. Do not use this device in close proximity to sources of strong electromagnetic radiation (e.g., unshielded intentional RF sources), as these can interfere with the proper operation. This equipment complies with the emission and immunity requirements of the IEC 61326 series.

CAUTION
Use the following procedure to install your system only if you are located in a region where Siemens Field Service Representatives do not perform installation.

After the system is installed, see *Configuring Operating Setup*, page 164 and the sections that follow for information about configuring the system.

Environmental Requirements

1. Place the system on a level surface and do not expose it to direct sunlight.
2. Ensure that the power connector and switch on the back panel are accessible.

See *Appendix F, Specifications*, for information about the physical dimensions, power requirements, and other physical and environmental specifications for the system.

Installation Procedure

For detailed figures, refer to *Section 10, Maintenance*.

1. Inspect the packing case and report any damage to the shipper. If you find any problems, notify your Siemens representative at installation.
2. Unpack the starter kit (common for Ca^{++}, Cl^{-} and Blood Gas) and check against the following list:

Description	Qty	Siemens Materials Number	Catalog Number	Article Number
Ready Sensor - Hct	1	10309783	106042	06553743
Ready Sensor - pCO_2	1	10317498	476247	02671199
Ready Sensor - pO_2	1	10324408	476246	06462640
Hct Slope	1	10309776	105670	06990590
Ready Sensor - pH	1	10312556	476267	07173251
Ready Sensor - Reference(Ref)	1	10323084	476273	05719400
RAPIDLab 348EX 6.8/ 7.3 Buffer	1	10309757	104227	01410308
RAPIDLab 348EX Wash	1	10309756	104226	02490356
Deproteinizer	1	10309775	105610	08915030

3. Unpack the Calcium starter kit and check against the following additional components:

Description	Qty	Siemens Materials Number	Catalog Number	Article Number
Ready Sensor - Calcium(Ca^{++})	1	10315922	476268	00061776
Ready Sensor - Sodium(Na^{+})	1	10312557	476266	09463893
Ready Sensor - Potassium (K^{+})	1	10327404	476270	08001888

4. Unpack the Chloride starter kit and check against the following additional components:

Description	Qty	Siemens Materials Number	Catalog Number	Article Number
Ready Sensor - Chloride(Cl^{-})	1	10330133	476268	00061776
Ready Sensor - Sodium(Na^{+})	1	10312557	476266	09463893
Ready Sensor - Potassium (K^{+})	1	10327404	476270	08001888

5. Unpack the Blood Gas starter kit and check against the following additional components:

Description	Qty	Siemens Materials Number	Catalog Number	Article Number
K^{+}/Ca^{++}/Cl^{-} Test/ Blank Sensor	2	10311665	673702	00768594
TEST/BLANK PH/NA^{+}	1	10311030	476281	05147202

WARNING

The system weighs 9.4 kg (20.7 lb). Observe safe lifting precautions.

6. Remove the system from the carton and place it on the work surface, with the back panel accessible.
7. If necessary, connect a suitable connector to the power supply cord.
8. Follow the connector manufacturer's instructions.

9. Insert the power supply cord into the power connector on the back panel.

CAUTION
Do not connect the power supply cord to the power supply.

Installing the Measurement Sensors

1. Ensure that the level of fill solution in the pH and K^+ (and Ca^{++} or Cl^-, if installing) sensors is full, with a small air space at the top.

   Note The Hct sensor does not require filling.

2. Ensure that the Na^+ sensor is completely full, with no air space.
   a. If necessary, empty and refill the sensors, making sure you use the correct fill solution.
   b. Follow the instructions on the fill solution pack.
   c. Make sure that no air bubbles are trapped in the bottom of the sensor.
   d. See *Refilling or Replacing the Measurement Sensors,* page 94.

   Note The gas sensors are sealed and cannot be refilled.

3. Raise the front cover.
4. Slide the measurement block catch down and raise the block door.
5. Insert the sensors in the following order:
   a. pO_2
   b. pCO_2
   c. Hct
   d. Na^+ or blank
   e. K^+ or blank
   f. Ca^{++} or Cl^- or blank
   g. pH

CAUTION
If you install a Ca^{++} or Cl^- sensor, you must select the appropriate measured parameter. See *Selecting Measurement Parameters,* page 169.

6. Slide the sensors into place, making sure that the sensor contacts align with the contacts in the block.

Installing the Reference Sensor

1. Refer to the reference sensor package insert for filling instructions.

CAUTION

- Make sure no air bubbles are trapped in the left chamber of the sensor cassette, immediately above the sample pathway.
- Do not overfill the right reservoir chamber.

2. Swing the block tensioner to the right and press the tensioner lock button to hold the tensioner in the open position.
3. Insert the reference sensor and push the bottom of the sensor to click it into place.
4. Make sure all the sensors are seated correctly, then hold the tensioner and press the tensioner lock button.
5. Gently release the tensioner and push it firmly home to make a good seal.
6. Lower the block door, snapping it into place.

Connecting the Pump Tubing

1. Tension the sample pump tubes (left pump) by pulling the tube lugs under the tensioners.
2. Connect the sample tube to the measurement block tube, and the waste tube to the manifold.
3. Connect the rubber connector to the manifold.
4. Tension the reagent pump tubes (right pump) by pulling the tube lugs under the tensioners.
5. Connect the rubber waste cap connector to the manifold.
6. Make sure that the pump tubing is not pinched.
7. Date the pump tubing labels a maximum of 3 months ahead.

Installing the Reagents

1. Remove the caps from the 6.8 and 7.3 buffer bottles.
2. Insert the tubing connectors into the bottles and push the caps onto the bottles.
3. Place the bottle assembly in the left side of the reagent compartment feeding the tubes through the caps into the solutions.

4. Date the buffer pack label a maximum of 21 days ahead.
5. Remove the User Action Pack from the neck of a Wash bottle and remove the bottle cap.
6. Insert the tubing connectors into the bottle and push the cap onto the bottle.
7. Place the bottle to the right of the buffer bottles feeding the tube through the cap into the solution.
8. Verify that the waste bottle is in position.
9. Verify that the neck of the waste bottle is correctly positioned underneath the rubber cap, with the waste cap spout inside the neck of the waste bottle.

Installing the Gas Cartridges

CAUTION

Use only Siemens gas cartridges supplied for use with the system, as they have been designed for ease of use and optimum performance. Siemens assumes no liability for performance if cartridges other than those specified for use with the system are used.

WARNING

Compressed gas cartridges require careful handling. To prevent damage and possible personal injury, observe the following precautions:

- Never install other gases, for example, propane cartridges.
- Never drop cartridges, allow them to strike each other or subject them to other strong shocks.
- Never tamper with the cartridge valves.
- Use these gases for the calibration of clinical and research instrumentation only. US Law prohibits dispensing these gases for drug use.
- The contents are under pressure—do not puncture.
- Do not use or store near heat or open flame.
- Do not expose cartridges to temperatures above 54°C (130°F), as this might cause the contents to vent or explode.
- Never throw cartridges into fire or incinerators. Dispose of the cartridges according to your laboratory protocol.

CAUTION

The cartridges and cartridge compartment are clearly marked and color coded:

- Gas 1 (blue)
- Gas 2 (black)

Ensure that the cartridges are installed in the correct position.

1. Remove the plastic protective cap from the cartridge valve.
2. Slide the cartridge into the compartment, and then gently push and turn the cartridge clockwise to engage it with the regulator.
3. Screw the cartridge in until finger tight.

   Note The gas regulator assembly is designed to make a good seal by finger tightening only. Do not overtighten the cartridges, either by using tools or by applying excessive force.
4. Lower the front cover.

Installing the Barcode Reader

The barcode reader requires no configuration before use.

Physical Installation

1. Connect the external barcode reader to the system through the USB port to enter patient ID data and Operator ID.
2. Attach the barcode reader bracket to the left or right side of the system.
3. Position the bracket so that you can comfortably use the scanner in one of the following ways:
   - Hand-held operation: you bring the scanner to the sample.
   - Fixed-position in the bracket: you bring the sample to the scanner.
4. When using the barcode reader, be sure to observe the safety precautions described in *Protecting Yourself from the Barcode Reader Beam*, page 24.

Setting the Barcode Reading Mode

In the default standard mode, you pull the trigger to read a barcode.

In presentation mode, the reader automatically reads any barcode in its field of view. In this mode, you can leave the reader on its bracket and pass the barcode in front of it.

To set the reader to presentation mode, scan the following barcode:

Figure 56: Presentation Mode Barcode

To reset the device to standard mode, scan the following barcode:

Figure 57: Standard Mode Barcode

To enable or disable Interleaved 2 of 5, scan the appropriate barcode below.

Figure 58: Enable Interleaved 2 of 5

Figure 59: Disable Interleaved 2 of 5

To enable or disable Codabar, scan the appropriate barcode below.

Figure 60: Enable Codabar

Figure 61: Disable Codabar

To enable or disable MicroPDF417, scan the appropriate barcode below.

Figure 62: Enable MicroPDF417

Figure 63: Disable MicroPDF417

Installing a USB Memory Stick

You can insert a USB memory stick into a USB port; for example, to install software.

Powering-Up the System

For information about powering up the system, see page 48. After the system completes its warmup, continue with the following steps to configure the system.

Configuring Operating Setup

Note When you have configured the system, print the setup report, page 171, so you have a record of the selected options.

1. Select **Ready > Settings > Operating Setup**.
2. Select the function that you want to set up.

Note The setup for dialysis fluid mode is the same as for blood gas mode, except that dialysis fluid mode has no reference ranges.

QC Ranges Setup

You can set QC ranges for 3 levels of QC and 2 levels of Hct QC. Level X has no ranges. If a QC measurement is outside these ranges a result is flagged on the display and on the printout.

You can set the system to prompt you via the Action List to run QC samples. The QC prompts appear at the times you select. Up to 3 prompts can be set. If a QC sample is prompted and is not run before the next prompt is due, subsequent sample results are flagged on the printout.

Default setting: instrument measurement range.

1. Select **Ready > Settings** > **Operating Setup > QC Setup**.
2. Select the QC level, then enter the lot number and ranges given in the QC product insert.

CAUTION
Changing QC lot clears the data file for that QC level. We recommend that you print the QC statistics (see page 71) before changing the lot.

The maximum QC range that can be entered is the instrument measurement range.

QC Prompts Setup

Default setting: no QC prompts set.

1. Select **Ready > Settings** > **Operating Setup > QC Setup** > **QC Prompts.**
2. Select the field and enter the time, in 24-hour, hh:mm format, at which you want each QC prompt to appear.

   You can set one, two, or three prompts.
3. To cancel the prompts and clear the value, select **C**.

Setting Reference Ranges

You can set reference ranges for all measured parameters. If a sample measurement is outside these ranges, the result is flagged on the display and on the printout.

Individual reference values can vary according to a number of factors such as age, posture, diet, exercise, and site of blood collection. We have taken these factors into account when establishing the default values for the system.

Default settings:

pH	7.350–7.450 (35.5–44.7 H^+ nmol/L)[6, 9, 11]
pCO_2	32.0–45.0 mmHg (4.27– 6.00 kPa)[6-10]
pO_2	75–100 mmHg (10.00–13.33 kPa)[6-8, 10]
Na^+	134–146 mmol/L[6, 7, 9-11]
K^+	3.40–4.50 mmol/L[6-7]
Ca^{++}	1.15–1.32 mmol/L[12, 13]
Cl^-	96–108 mmol/L[6-11]
Hct	34–52%[6, 7, 11]

Each laboratory should establish its own reference ranges.

1. Select **Ready > Settings** > **Operating Setup > Reference Ranges**.
2. Select the parameters for which you want to set the range.

   If you do not want to use the reference range facility, set the range to the maximum instrument measurement range.
3. Enter the reference range for each selected parameter.

   The maximum range that can be entered is the instrument measurement range. See *Measurement Range,* page 203.
4. Select **Ready > Settings > Operating Setup > Units**.
5. Select the units that you want to use:
   - pH units (default) or H^+ nmol/L
   - mmHg (default) or kPa for gases
   - g/dL (default), g/L, or mmol/L for *c*tHb (entered and estimated).

Configuring Calibration

For information about configuring calibration timing (method and interval) and gas values, see *Selecting Calibration Method and Entering Gas Values,* page 63.

Setting Printer Options

1. Select **Ready > Settings > Operating Setup > Printer Options**.
2. Select the printer options:
   - Turn the roll printer on (default) or off.
   - Print results (default), calibrations, or calibration summary, or any combination of these options.
   - If you select cal summary, the system prints the cal summary at approximately 6 A.M. each day.
   - Print 1 (default), 2, or 3 copies of the sample report.

   Note The number of copies option refers only to results. The system prints all other data only once.

Adjusting Correlation

The system is set during manufacture to give results that correlate with the following values:

pH	high precision pH system (Model R)
pCO_2 and pO_2	tonometered blood
Na^+ and K^+	flame photometry (480)
Ca^{++}	ISE (634)
Cl^-	coulometry (925)
Hct	microcentrifuge

CAUTION

To change the values to correlate with other analyzers, you must use the following procedure:

1. Reset the correlation factors in the system to:
   pH, pCO_2, pO_2, Na^+, K^+, Ca^{++}, Cl^-, and Hct slope = 1.000
   pH, pCO_2, pO_2, Na^+, K^+, Ca^{++}, Cl^-, and Hct intercept = 0.000
2. Use a large sample population covering the physiological range—minimum 50 samples, preferably 100—to generate a random distribution of values (not just normal values).
3. Make sure that the system and the reference analyzers are calibrated following the manufacturer's instructions and are operating within specifications.
4. Store samples at room temperature and measure them within 30 minutes of collection. Samples should be analyzed in duplicate on both analyzers, with no more than 5 minutes between analysis on the system and analysis on the reference analyzers.
5. Remove outliers from the data (means of duplicates values outside ±3SD, or duplicates that differ).
6. Perform a linear regression analysis. We recommend the Deming method, which accounts for errors on both axes. Perform the linear regression using a regression program on a calculator or computer. The system should be treated as the dependent variable (Y-axis), or the variable on the left side of the equation.

Note The X variable should be the reference analyzer.

7. The intercept and slope values obtained can then be entered using the Correlation routine.

Note Values can be entered into the Correlation routine only in pH units and mmHg. If you use H^+ nmol/L or kPa for measurement, you must convert these values into pH units and mmHg before entering.

- To convert from H^+ nmol/L to pH: pH = 9.0 - log10(H nmol/L)

To convert to mmHg from kPa: mmHg = kPa x 7.50062

1. Select **Ready > Settings** > **Operating Setup > Correlation**.

   To change dialysis fluid mode parameters, first select **Ready > DF**, so that you see the message: Lift probe to analyze dialysis fluid.

2. Enter the value or values that you want to change:

Parameter	Value	Default value for pH, pCO_2, pO_2, Na^+, K^+, Ca^{++}, and Cl^-
slope	0.5–1.5	1.000
intercept	±5.000	0.000

Note Although you can change the correlation of other parameters on the **Dialysis Fluid Correlation** screen, those values are not used for any measurement purposes.

Configuring System Setup

To configure system setup functions, select **Ready > Settings > System Setup**.

Changing Date and Time

1. Select **Ready > Settings > System Setup > Date and Time.**

   The date and time of calibrations and measurements appear on the printout. Changing the date and time clears the data held in the calibration summary.

2. To keep a record of all calibrations, print the calibration summary, page 66, before changing the date and time.

Default setting: Date and time set.

Setting the Maintenance Prompts

The system prompts you via the Action List to empty the waste bottle and to deproteinize and condition the sensors. The prompts appear at approximately 6 A.M. at the intervals you select.

1. Select **Ready > Settings > System Setup > Maintenance Prompt**.
   - Waste bottle prompt, range: 0–9 days. Default: empty the waste bottle every day.
   - Deproteinize/condition prompt, range: 0–21 days. Default: every 14 days.
2. To cancel the prompts, enter 0 or select Cancel to clear the value.

Selecting Measurement Parameters

1. Select **Ready > Settings > System Setup > Parameters**.
2. For blood gas mode, select parameters to measure by selecting **Measured** and choose from the following options:
   - pH
   - pCO_2
   - pO_2
   - Na^+
   - K^+
   - CA^{++}
   - Cl^-
   - Hct

CAUTION
Do not select Ca^{++} or Cl^- unless you have the appropriate sensor installed. If you install either a Ca^{++} or Cl^- sensor, make sure you select the correct measured parameter.

Note By default, the pH, pCO_2, pO_2, Na^+, K^+ and Hct measurement channels are selected. Ca^{++} and Cl^- are not selected. The system does not allow you to turn off all channels.

3. For dialysis fluid mode, select parameters to measure by selecting **Measured** and choose from the following options:
   - pH
   - pCO_2
   - Na^+
   - K^+
   - Ca^{++}

Selecting Calculated Parameters

Calculated parameters are displayed only if the appropriate measurement channels are selected. By default, no calculated parameters are selected.

1. To select the acid/base parameters to calculate, select **Ready > Settings > System Setup > Parameters > Calculated (Acid-Base)** and choose from the following options:
   - HCO_3^-act
   - BE(ecf)

- $ctCO_2$
- AnGap
- HCO_3^-std
- BE(B)
- Ca^{++}(7.4)

Note BE(ecf) was formerly BE(vv), and BE(B) was formerly BE(vt).

2. To select the oxygenation status parameters to calculate, select Calculated (Oxygenation) and select from the following options:
   - O_2SAT
   - ctHb (est)
   - pO_2(A-a)
   - O_2CT
   - pO_2/F_IO_2
   - pO_2(a/A)

   Note pO_2(A-a) was formerly A-aDO_2, and pO_2(a/A) was formerly a/A ratio.

   O_2CT is displayed only if ctHb is entered, or ctHb(est) is available. Parameters pO_2(A-a), pO_2(a/A) and pO_2/F_IO_2 are displayed only if F_IO_2 is entered.

Turning the Beeper Off or On

1. Select **Ready > Settings > System Setup > Beeper**.
2. Select **Beeper On** (default) or **Beeper Off**.

Changing Communication Options

The system has 2 data ports. You can configure both ports to your requirements. Port 2 supports only the LIS 1 protocol. See *Appendix F, Interfacing to External Devices* for detailed information.

1. Select **Ready > Settings > System Setup > Communications**.
2. To set the protocol to use for Port 1, select **Port 1 Protocol**, then select 1 of the following options:
   - LIS 1 (default)
   - LIS 2
   - LIS 3

Note Selecting a different protocol for a port overwrites previous selections.

3. To set the options for Port 1, select **Port 1 Options**, then select the appropriate parameters:

Parameter	Default Value
Baud rate	9600 baud
Stop bits	1 start bit, 8 data bits, 1 stop bit
Parity	Off

4. To set the protocol to use for Port 2, select **Port 2 Protocol,** then select **LIS 1** as the protocol.

   Note LIS 1 is the only acceptable protocol for Port 2.

Setting Security

Requiring an operator ID protects the measurement sequence. Password protection guards against unauthorized or accidental changing of setup options.

Even without entering a required password, you can do sample and QC measurement, and the system calibrates as required. You can return to the Ready screen without entering the password.

1. Select **Ready > Settings > System Setup > Security**.
2. Select **Menu Password**.
3. Enter a menu password, up to 8 digits.

   Use the hyphen to insert dashes.

   Note If you forget the password, you can use the master password: 0066838.
4. To require that the user enter an operator ID, select **Security > Operator ID**.
5. Select **On** or **Off** (default).

Printing the Setup Report

When you have finished configuring the system, print the setup report, showing all the setup options:

1. Select **Ready > Settings > System Setup > Print Setup Report**.
2. Keep the setup report in a place where you can refer to it as needed.

Service Setup

1. Select **Ready > Settings > Service Setup**.
2. Select **System Information, Language Selection,** or **Software Update**.

Entering System Information

Use the system information parameters to keep a record of the system serial number, software revision, and service contact telephone number. The system automatically records the software revision.

1. Select **Ready > Settings > Service Setup > System Information**.
2. Enter the service telephone number (up to 12 digits).

   By default, the service telephone number is blank.
3. Enter the system serial number (4 digits).

Changing Language

1. Select **Ready > Settings > Service Setup > Language Selection**.
2. Select the appropriate language.

   English is the default language selection.

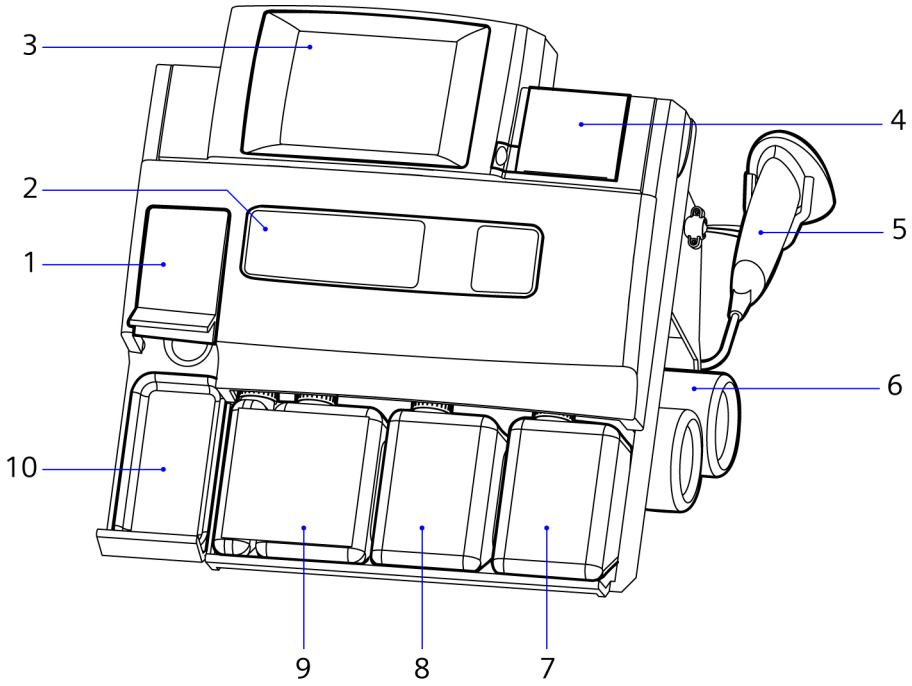
Note Changing the language clears the data held in the calibration summary. If you want to keep a record of all calibrations, print the calibration summary, page 66, before changing the language.

Appendix A: Concepts and Reference Information

This appendix contains conceptual and reference information underpinning the procedural information earlier in this book.

RAPIDLab 348EX System Overview

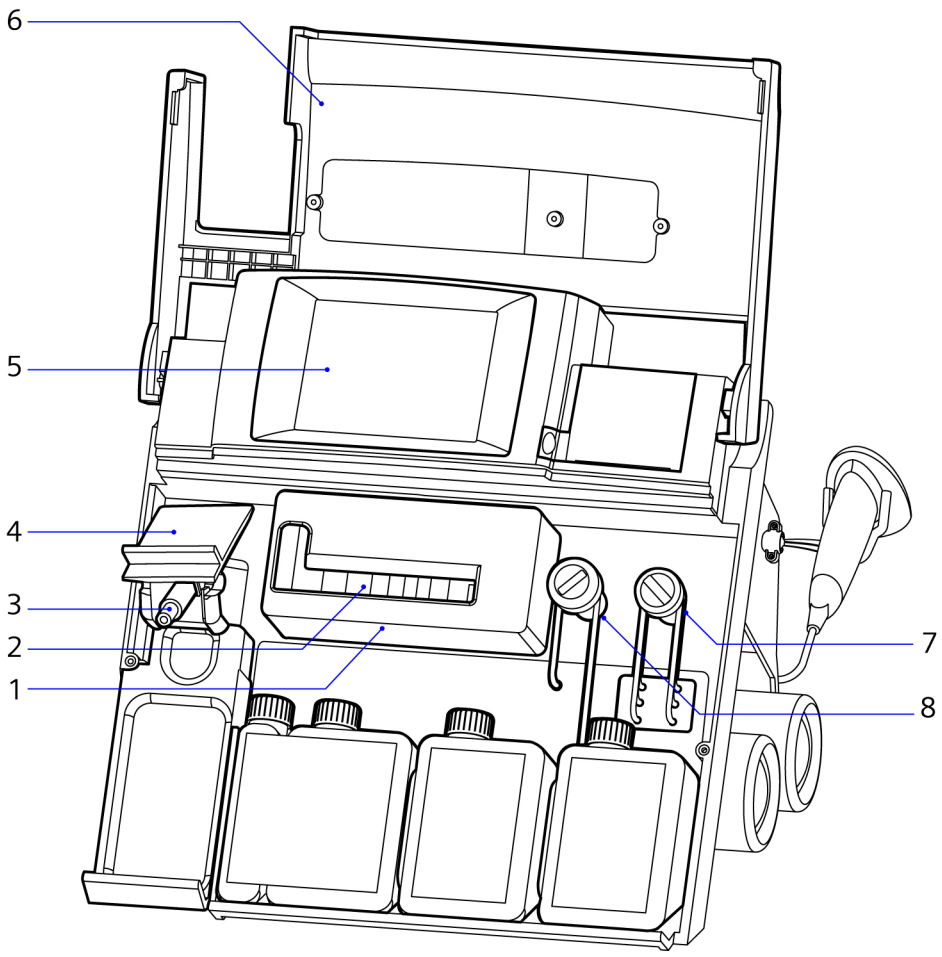
Figure 64: RAPIDLab348EX System Front View



1. Probe lever (closed)
2. Measurement block window (front cover closed)
3. Touch screen
4. Printer cover
5. Barcode reader
6. Gas cylinders
7. Waste bottle
8. Wash reagent

9. 6.8/7.3 Buffer
10. Drip tray

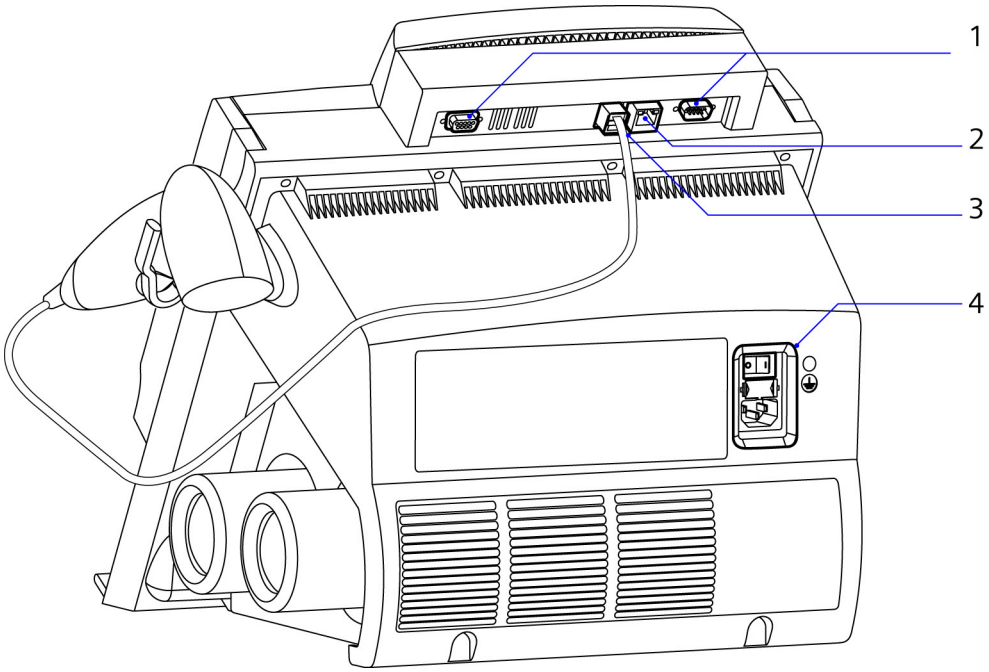
Figure 65: RAPIDLab 348EX System, Cover Raised



1. Measurement block door
2. Sensors
3. Probe
4. Probe lever (open)
5. Touch screen
6. Front cover (raised)
7. Reagent pump
8. Sample pump

The Back Panel

Figure 66: The Back Panel



1. RS-232 Ports (9-way, D-line)
2. Ethernet port (reserved for Siemens use)
3. USB ports
4. Power module (on-off switch, power connector and fuses)

The system has no internal user-replaceable parts. Do not remove the back cover from the system.

Back Panel Symbols

Appendix G, Symbols describes the symbols that appear on the back of the system.

Using the Touch Screen

You interact with the system through an integrated touch screen display. The touch screen displays messages, options, and requests for information. You respond by selecting a button or an area on the touch screen.

The information displayed on the touch screen leads you through the necessary steps to analyze samples, or to use any of the other functions.

To extend the life of the screen, the system dims the display brightness after 10 minutes of inactivity and whenever the system is in Standby mode. You can adjust the display brightness to suit your needs.

CAUTION

Do not use anything hard or pointed on the touch screen. Doing so might damage the screen.

Menu Map

The touch screen displays a series of menus and display screens that let you navigate through the system functions, select and perform specific actions, and display results. The following table summarizes the principal menus.

Parent Screen	Leads to
Ready	• Syringe, Capillary, QC, and Dialysis Fluid analyses
	• Settings/Main Menu
	• Action List
Main Menu	• Calibration
	• Maintenance
	• Troubleshooting
	• Data Recall
	• Operating, System, and Service Setup
	• Standby
Action List	• Sensors
	• Deproteinize
	• Condition
	• Hct Slope
	• Gas
	• Printer
	• QC
	• Waste Bottle

Each of these menus leads to a series of submenus relevant to your selections.

Main Menu Options

To navigate to the Main Menu, select the Settings icon  on the Ready screen. The Main Menu provides access to submenus that let you calibrate the system, set up operational parameters such as units, printer options, reference ranges, correlations, and QC levels and prompts, recall data, perform troubleshooting, and set up system parameters.

Action List

To display the Action List screen, select  from the Ready screen. The system prompts you to carry out various tasks associated with the Action List. On the Main Menu, you can configure how often some of these prompts appear; for example, Deproteinize, Condition, QC and Waste Bottle. Other prompts appear when the system detects that user action is required: Sensors, Hct Slope, Gas and Printer.

Action Required prompts appear over the Ready screen. For example, If the system deselects a sensor because it has not passed a calibration, the display shows which sensor is unavailable. The Action List displays the user action required for Sensors.

Note The system suspends the system's functions while it is displaying the Action List, so you can replace the gas cartridges and empty the waste bottle without stopping the system.

Calibration Overview

The system automatically calibrates using one of the following user-selectable methods.

- Calibration drift
- Slope drift
- Calibration endpoint
- Slope endpoint
- Calibration range
- Slope range

Five minutes before a calibration is due, the Ready screen shows a countdown message indicating the time until the next calibration. You can still measure samples during this time.

For Information About	Go Here
Calibration Setup	Section 8, *Calibrating Your System*
Troubleshooting	Section 11, *Troubleshooting*
Selecting Calibration Method and Timing	"Selecting Calibration Method and Entering Gas Values" on page 63

Sensor Deselection

If a sensor fails calibration, the system deselects it, and it is not available for sample or QC measurement. The deselection is flagged on the Ready screen and, when first deselected, on the calibration printout.

The system monitors deselected sensors, and automatically reselects them if they subsequently meet the calibration specifications.

Note The system does not calibrate while in standby mode, but it automatically calibrates as required when restarted, before allowing sample measurements.

Calibration Setup Options and Values

Default Calibration Setup Options and Values

method	time	flexible	
	interval	30 minutes	
gas values	cal	5% CO_2	12% O_2
	slope	10% CO_2	0% O_2

Calibration Gases

Two gas standards are used to calibrate the pCO_2 and pO_2 sensors.

Gas 1 (cal)	Provides the calibration point for 1- and 2-point pCO_2 and pO_2 calibrations. The Cal Gas cartridge contains 5.00 ± 0.05% carbon dioxide and 12.00 ± 0.05% oxygen, balanced with nitrogen, and is NIST traceable.
Gas 2 (slope)	Provides the slope point for 2-point pCO_2 and pO_2 calibrations. The Slope Gas cartridge contains 10.00 ± 0.05% carbon dioxide balanced with nitrogen, and is NIST traceable.

For information about safely handling gas cartridges, see *Changing the Gas Cartridges,* page 86.

Selecting Calibration Method and Entering Gas Values

The calibration options let you:

- Choose the timing method the system uses when it calibrates.
- Select the maximum time interval between calibrations.

  Siemens recommends that you set the calibration interval to 30 minutes.
- Enter non-Siemens gas values.

To set the calibration options, perform the actions listed in *Selecting Calibration Method and Entering Gas Values,* page 63.

Recalling and Printing Calibration Data

The system maintains a calibration summary for all calibrations within a 24-hour period. The data includes the following values:

- System ID, time and date

- Calibration summary interval
- Number of calibrations (including manually initiated calibrations)
- Calibration status. Any failed calibrations are detailed.
- Time, date, calibration number, and calibration report for any failed calibration

You can print a calibration summary in the following ways:

- Automatically, by configuring the printer setup options to print the summary every day at the end of the first calibration after 6 am. See *Setting Printer Options,* page 166 and *Manually Printing a Calibration Summary,* page 66.
- Manually, by performing the actions described in *Manually Printing a Calibration Summary,* page 66.

Requesting Additional Calibrations

The system automatically calibrates using one of the user-selectable methods. See *Calibration Setup Options and Values,* page 179.

The Calibration menu lets you perform additional, user-requested calibrations. See *Selecting Calibration Method and Entering Gas Values,* page 63.

Each type of calibration has its own screen displaying type of calibration in the header line and the calibration values for the currently running calibration type. The text updates dynamically to inform you which part of the calibration cycle is being carried out.

Quality Control

See *Chapter 10, Quality Control*, for a full description of quality control procedures. You can use the Data Recall menu to perform the following functions:

- Printing statistical data for Levels 1 - 3 and Hct Levels A and B
- Recalling data for each QC sample
- Reassigning QC data to another level
- Printing results for each QC sample

Setting Reference Ranges (All Measured Parameters)

You can set reference ranges for all measured parameters.

If a sample measurement is outside these ranges, the result is flagged on the display and on the printout.

Individual reference values can vary according to a number of factors such as age, posture, diet, exercise and site of blood collection. We have taken these factors into account when establishing the default values for the system.

See the following section for more detail about values used for reference ranges.

Reference Ranges

Reference Ranges, also known as Reference Intervals, are guidelines only and should not be considered as the sole indicator of health and disease. Reference ranges can be affected by a number of factors, such as age, gender, diet, exercise, site of blood collection, and a patient's normal physiological condition. Each facility should define the reference ranges that are applicable to their patient populations. Reference Intervals for the assays are shown in the table below.

The values provided on the following pages are derived from the technical literature. For a list of citations from the technical literature, see *Appendix E, References*[46-53]

Reference Ranges Table

Analyte	Units/Alternate Units of Measurement	Reference Interval
pH	pH	7.350–7.450[a]
H^+	nmol/L	44.7–35.5
pCO_2	mmHg	32.0–48.0[b]
	kPa	4.27–6.40
pO_2[c]	mmHg	83.0–108.0[d]
	kPa	11.07–14.40
Na^+	mmol/L	136.0–145.0
K^+	mmol/L	3.40–4.50
Ca^{++}	mmol/L	1.15–1.33
	mg/dL	4.6–5.3
Cl^-	mmol/L	98–107
Calculated Parameter	**Units/Alternate Units of Measurement**	**Reference Interval**
Hct	%	36–52[e]
	decimal	0.36–0.52
HCO_3^- (act)	mmol/L	21.0–28.0[f]
HCO_3^- (std)	mmol/L	21.0–28.0[f]
BE (ecf)	mmol/L	-2.0 - +3.0
BE (B)	mmol/L	-2.0 - + 3.0
sO_2	%	94.0–98.0[g]
	decimal	0.940-0.980
AnGap	mmol/L	10.0–18.0 Using equation (Na + K)–(Cl + HCO_3^-)
$ctCO_2$	mmol/L	22.0–29.0

a. Includes children and adults < 60 years; arterial at 37°C.

b. Gender specifics exist: Female 32.0–45.0 mmHg, Male 35.0–48.0 mmHg.

c. **Important:** pO_2 results from an arterialized capillary may be unreliable.

d. Includes from 2 days to 60 years.

e. Gender specifics exist: Adult female 36–47%, Adult male 40–52%.

f. Plasma

g. This is the range for adults. The range for newborns is: 40–90%.

Configuring the System

Use the setup options on the Main Menu to configure the way you want your system to work. *Chapter 10,* System Installation and Configuration describes the configuration process in detail.

Setting Security

To protect the measurement sequence, you can configure the system to require the user to enter an operator ID, and you can select password protection for the Main Menu.

Requiring an Operator ID

The operator ID requirement protects sample and QC analysis. If the operator ID-required option is selected, every sample and QC analysis prompts you to enter your ID number. The operator ID number is printed on sample and QC reports. Analysis does not continue until an operator ID number has been entered.

Requiring a Menu Password

The menu password protects the Main Menu and guards against unauthorized or accidental changing of setup options. The system allows sample and QC measurement, and calibrates as required. If the menu security option is enabled, the system prompts you to enter the password. Menu access is prevented until the password has been entered correctly. You can return to the Ready screen without entering the password.

Appendix B: Warranty and Support Information

Standard Instrument Warranty and Service Delivery Policy

Siemens and its authorized distributors provide customers who acquire new Siemens instruments with a one-year comprehensive, but limited, warranty. This limited warranty is designed to protect customers from the cost associated with repairing instruments that exhibit malfunctions due to defects in materials and/or workmanship during the warranty period.

Warranty Period

The warranty period commences upon installation at the customer's location and extends for a period of one year thereafter. The customer, with some exceptions, may purchase additional service coverage beyond the one year warranty period as part of the original instrument acquisition for second or subsequent years beyond the original installation date. The customer's original Purchase Invoice or appropriate Agreement Addendum must indicate the term in months for additional service coverage.

Warranty Service During Normal Business Hours

The customer may obtain warranty service for instruments during normal business hours by contacting the Siemens location or authorized distributor. Refer to the list of Siemens locations in this section.

Extent of a Warranty Service Call

During the warranty period, Siemens (or an authorized distributor) will repair the instrument during normal business hours, at their expense, subject to the exclusions listed below. Siemens or an authorized distributor will initiate a warranty field service call when notified. The call will be considered complete when the instrument is again operating to its published specifications and the customer, or the customer's representative, has agreed by signing the appropriate Field Service Report. When service is complete, the customer will receive a copy of the Field Service Report detailing all work performed by the Siemens representative.

Warranty Service Outside Normal Hours

Customers, with some exceptions, may also request warranty service to be delivered outside of normal business hours, including evenings, weekend days, or nationally observed holidays by contacting the Siemens location or authorized distributor. Warranty service performed at these times is subject to a surcharge unless the customer has purchased a service product option that provides warranty service outside normal hours.

Replacement of Parts

In performing warranty service under this agreement, Siemens or its authorized distributors will provide appropriate parts to repair the instrument at no charge with the exception of certain parts or subassemblies that are considered Customer Maintenance Items. Customer Maintenance Items include, but are not limited to, the following items: lamps, electrodes or sensors (which are covered by a separate warranty), Siemens reagents and calibrators, controls, pump tubing kits, paper and pens. Consult the appropriate operator's manual for a complete list of maintenance items for any specific model of instrument.

Design Changes and Retrofitting of Instruments

During the warranty period, Siemens reserves the right to change the design or construction of specific models of instruments without incurring any obligation to make such changes available to an individual instrument. If Siemens notifies customers of a change that improves the performance or reliability of their instrument, and requests to retrofit that instrument, customers must agree to allow Siemens or an authorized distributor, at Siemens expense, to retrofit components or make design changes, which will not adversely affect the instrument's performance characteristics.

Key Operator Designation

Customers will designate a key operator who will be available to Siemens representatives to describe instrument malfunctions by telephone and/or to perform simple adjustments and corrections as requested. If a key operator is not designated or is unavailable when the customer requests service, the delivery of warranty service may be delayed.

OSHA Requirements (US only)

When service is required at a customer location, the customer must provide the Siemens representative with adequate facilities that comply with the regulations of the Secretary of Labor under the Occupational Safety and Health Act (OSHA) of 1970, as amended.

Warranty Exclusions

Siemens or its authorized distributors will provide warranty service to customers during the warranty period, which includes appropriate parts, travel to the location of the instrument, and on-site labour during normal business hours. In addition, Siemens or its authorized distributors will provide warranty service during the warranty period only, and instrument repairs, labour or replacement parts, as provided during the original warranty period, will not extend the original warranty period.

Warranty Exclusions

This warranty does not apply if any of the following occurs:

1. Repairs or modifications have been made to the instrument by other than an authorized Siemens representative.
2. The instrument has been operated using other than Siemens brand accessories, or consumable supplies and/or reagents not having the same grade, quality, and composition as defined by Siemens.
3. The instrument has not been installed within 90 days of shipment to the customer's facility unless otherwise specified.
4. The customer has not performed appropriate customer maintenance procedures, as outlined in the instrument operator's manual.
5. The instrument has been misused or used for a purpose for which it was not intended.
6. The instrument has been damaged in transit to the customer or damaged by the customer while moving or relocating it without supervision by a Siemens representative.
7. Damage was caused by floods, earthquakes, tornadoes, hurricanes or other natural or man-made disasters.
8. Damage was caused by Acts of War, vandalism, sabotage, arson, or civil commotion.
9. Damage was caused by electrical surges or voltages exceeding the tolerances outlined in the instrument operator's manual.
10. Damage was caused by water from any source external to the instrument.
11. The customer has purchased an alternative agreement whose terms of warranty supersede this agreement.

Siemens or its authorized distributors will invoice customers, at current standard labour and parts rates, for instruments repaired to correct damage or malfunctions due to any of the reasons listed above.

Limitations of Siemens Original Warranty

Siemens warrants to all customers that service will be performed in a professional manner consistent with the industry. If the instrument is not performing according to its specifications, Siemens will, at its option, repair or replace the instrument. This is the customer's sole and exclusive remedy for breach of warranty.

Other than as stated above, there are no other warranties, express or implied, accompanying either the leasing of the equipment or its sale to the customer at the expiration or termination of this agreement. In addition, the warranties of merchantability and fitness for a particular purpose are disclaimed. In addition, Siemens shall not be liable for any damages caused by delay in providing repair service from any cause. Siemens liability for breach of this warranty shall be limited to the repair or replacement of defective equipment and shall not include any incidental, contingent, or consequential damages.

IT Security

See the product’s Security White Paper and MDS2 for additional information about specifications for software, hardware, network characteristics, and security controls. This technical information is not part of the operator guide, and is intended for the information technology or security professional. Security White Paper and MDS2 can be found at siemens-healthineers.com/poc or contact your local technical service provider.

Disposal of the Analyzer

The instrument must be treated as biological contaminated hazardous waste. Proper disposal of old instruments (including its plastic parts, electrical components) prevents potential negative consequences for the environment and human health. All electrical and electronic products and other components of the analyzer should be disposed of separately from the municipal waste system. Final disposal must be organized in a way that does not endanger waste handlers. As a rule, such equipment must be sterile before it is passed for final disposal. For more information about disposal of such product, please contact your city office, waste disposal service, or your local safety officer.

Technical Assistance

For technical assistance, customer service, or additional information, contact your local technical provider or distributor.

siemens-healthineers.com/poc

The summary of safety and performance for this *in vitro* diagnostic medical device is available to the public in the European database on medical devices (EUDAMED) when this database is available and the information has been uploaded by the Notified Body. The web address of the EUDAMED public website is: https://ec.europa.eu/tools/eudamed.

According to EU regulation 2017/746, any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the EU Member State in which the user and/or patient is established.

Training

This guide describes the proper use and operation of the system. System operators and administrators should familiarize themselves with the applicable sections in the manual prior to conducting testing to assure safe and effective use of the system. As training requirements for this device vary by country and region, make sure you follow any training in accordance with local, federal, or country laws and regulations. If you require further information about training in the use of this product, contact your local Siemens Healthineers representative.

Appendix C: Orderable Supplies

Ordering Information

When ordering supplies, please give the following information to your local distributor:

- System serial number (To locate the serial number, see *Entering System Information,* page 172.)
- Article number of part
- Description
- Quantity required

This ensures that your order is dealt with quickly and efficiently. The number shown in the Quantity column is the number of items supplied against that catalog number. If the quantity is more than 1, only multiples of that number can be supplied. For a comprehensive list of service spares, see the Service Manual.

Orderable Spares

Description	Quantity	REF
Ready Sensor - Reference Inner	1x Reference Electrode Inner, 1x Container, 1x 5ml RAPIDLab Reference Electrode Fill, 1x Dispensing Tip, 1x Insert	10329947 (478509) (09388182)
Ready Sensor - Ref Refill	1x Reference Sensor Cassette, 1x Container, 1x 5ml RAPIDLab Reference Electrode Fill, 1x Dispensing Tip, 1x Insert	10320458 (10320458) (04273425)
Probe and tubing kit	1x Probe and Tubing kit	10309797 (107275) (01880878)
Probe and housing kit	1x Probe and Housing kit	10311628 (673253) (06152072)
Probe protectors	10x Probe protectors	10324749 (673373) (06565849)
Bottle tubing kit	1x Bottle Tubing Kit	10309778 (105672) (06865362)
Sample pump tubing kit	1x Sample pump tubing kit	10309780 (105674) (00782481)
Reagent pump tubing kit	1x Reagent pump tubing kit	10309781 (105675) (04376879)
Sample and reagent pump tubing kit	1x Sample and reagent pump tubing kit	10309779 (105673) (04814094)
Clot removal line, 0.5 m (19 1/2 inches)	1x Clot removal line pack	10311063 (478645) (07110136)
Drip tray	1x Drip tray	10311630 (673255) (03521867)
Ready Sensor - pH	1x pH Electrode, 2x 3ml RAPIDLab 348EX pH Electrode Fill, 1x O-rings	10312556 (476267) (07173251)
Ready Sensor - pCO_2	1x pCO_2 Electrode, 2x O-rings	10317498 (476247) (02671199)
Ready Sensor - pO_2	1x pO_2 Electrode, 1x O-rings	10324408 (476246) (06462640)

Description	Quantity	REF
Ready Sensor - Sodium (Na^+)	1x Sodium Electrode, 2x 3ml RAPIDLab 348EX $Na^+/K^+/Ca^{++}/Cl^-$ Electrode Fill, 1x O-rings	10312557 (476266) (09463893)
Ready Sensor - Potassium (K^+)	1x Potassium Electrode, 2x 3ml RAPIDLab 348EX $Na^+/K^+/Ca^{++}/Cl^-$ Electrode Fill, 1x O-rings	10327404 (476270) (08001888)
Ready Sensor - Calcium (Ca^{++})	1x Calcium Electrode, 2x 3ml RAPIDLab 348EX $Na^+/K^+/Ca^{++}/Cl^-$ Electrode Fill, 1x O-rings	10315922 (476268) (01810225)
Ready Sensor - Chloride (Cl^-)	1x Chloride Electrode, 2x 3ml RAPIDLab 348EX $Na^+/K^+/Ca^{++}/Cl^-$ Electrode Fill, 1x O-rings, 1x Insert	10330133 (476279) (00183065)
Ready Sensor - Hct	1x Hct Sensor	10309783 (106042) (06553743)
Ready Sensor - Reference (Ref)	1x Reference Sensor Cassette, 1x Reference Electrode Inner, 1x Container, 1x 5ml RAPIDLab Reference Electrode Fill, 1x Dispensing Tip, 1x Insert	10323084 (476273) (05719400)
Gas Cartridge Pack	1x Gas Cartridge	10309768 (105070) (00384192)
Gas cartridge venting tool	1x Gas cartridge venting tool	10314899 (107678) (01255779)
Gas cartridge removal tool	1x Gas cartridge removal tool	103295329(107679) (09171841)
Test/Blank sensor $K^+/Ca^{++}/Cl^-$ (TB3)	1x $K^+/Ca^{++}/Cl^-$ Test/Blank Sensor, 1x O-rings	10311665 (673702) (00768594)
Test/Blank sensor pH/Na^+ (TB2)	1x pH/Na^+ Test/Blank sensor	10311030 (476281) (05147202)
Test/Blank sensor ref (TB5)	1x Ref Test/Blank sensor, 1x O-rings	10327492 (673396) (08053446)
Pre-heater tube kit	1x Pre-heater tube kit	10309777 (105671) (01109527)
Fluid detector 1 (serial numbers below D001 only)	1x Fluid detector 1	10311637 (673266) (00659477)

Description	Quantity	REF
Fluid detector 2 (serial numbers below D001 only)	1x Fluid detector 2	10311663 (673359) (06864900)
Fluid detector 1 (serial numbers above D001 only)	1x Fluid detector 1	11046693
Fluid detector 2 (serial numbers above D001 only)	1x Fluid detector 2	11046694
Printer paper	5 rolls	10314709 (673252) (01150195)
Service manual	1x Service manual	NA
Operator's Guide, English	1x English Operator's Guide	10698291
Operator's Guide, Japanese	1x Japanese Operator's Guide	10698295
RAPIDLab 348EX System Interface Manual, English	1x English Interface Manual	10698304
RAPIDLab 348EX System Interface Manual, Japanese	1x Japanese Interface Manual	10698307
RAPIDLab 348EX Documentation CD	1x Documentation CD	11046591
Power cord, USA/Canada	1x Power cord	11556657
Power cord, EU/RUS/KOR	1x Power cord	11556662
Power cord, UK + Ireland	1x Power cord	11556663
Multicap 140 µl	50x 140µl Multicap, 1x Insert	10314796 (473193) (01198961)
Multicap 140µl	500x 140µl Multicap, 1x Insert	10311005 (473646) (06493996)
Caps	100x Caps	10311054 (478605) (01158100)
MULTICAP blood collection kit, containing 100x 60µl capillary tubes and 200 caps	100x 60µl capillary tubes, 200x caps	10314213 (473823) (00855578)
Multicap 100µl	50x 100µl Multicap, 1x Insert	10323539 (673394) (05974729)
Multicap 100µl	500x 100µl Multicap, 1x Insert	10322912 (108758) (05614986)

Description	Quantity	REF
pH/bloodgas blood collection capillary tubes, 100x 100µl capillaries	100x 100µl capillaries	10310990 (471836) (08851318)
Multicap-S Plastic Capillaries	50x 100µl Multicap-S Plastic Capillaries, 1x Insert	10313252 (335434) (00335434)
Multicap-S Plastic Capillaries	500x 100µl Multicap-S Plastic Capillaries, 1x Insert	10322986 (5656514) (05656514)
Multicap-S Plastic Capillaries	50x 140µl Multicap-S Plastic Capillaries, 1x Insert	10320937 (4549544) (04549544)
Multicap-S Plastic Capillaries	500x 140µl Multicap-S plastic Capillaries, 1x Insert	10313226 (325811) (00325811)
Multicap-S Plastic Capillaries	50x 175µl Multicap -S Plastic Capillaries, 1x Insert	10324363 (6440221) (06440221)
Multicap-S Plastic Capillaries	500x 175µl Multicap-S plastic Capillaries, 1x Insert	10316361 (2043295) (02043295)
Capillary Caps	200x Capillary Caps	10311053 (478601) (01687040)
Adaptors for capillaries, pack of 100	100x Capillary Adapters	10330785 (478647) (09851273)

Reagents

Description	Quantity	REF
RAPIDLab 348EX 6.8/7.3 Buffer	4x 6.8 Buffer Bottle (90mL), 4x 7.3 Buffer Bottle (370ml)	10309757 (104227) (01410308)
RAPIDLab 348EX 6.8/7.3 Buffer (Japan)	4x 6.8 Buffer Bottle (90ml), 4x 7.3 Buffer Bottle (370ml)	10336723
RAPIDLab 348EX Wash	4x 450ml Wash Bottle, 4x 2ml Deproteinizer, 4x 50mg Pepsin, 4x 2ml conditioner, 4x 2ml Hct slope	10309756 (104226) (02490356)
Wash Pack (Japan only)	4x 450ml Wash Bottle	10329872 (106370) (09349799)

Description	Quantity	REF
Hct Slope	10x 2ml Hct Slope	10309776 (105670) (06990590)
Deproteinizer Kit	10x Deproteinizer	10309775 (105610) (08915030)
Conditioner Kit	5x 2ml Conditioner	10311078 (478701) (02578644)
RAPIDLab 348EX pH Electrode Fill	3x 3ml RAPIDLab 348EX pH Electrode Fill	10311046 (478533) (06386650)
RAPIDLab 348EX $Na^+/K^+/Ca^{++}/Cl^-$ ElectrodeFill	3x 3ml RAPIDLab 348EX $Na^+/K^+/Ca^{++}/Cl^-$ Electrode Fill	10311047 (478535) (08999595)
RAPIDLab Electrode Fill Solution, Reference	4x 5ml RAPIDLab Reference Electrode Fill	10311081 (478822) (02563698)
Calibration Verification Material (CVM)	20x 2.5ml Ampules (4 each level), 25x PSQA, 1x Data collection form, 1x Insert	10316535 (116189) (02147872)
RAPIDQC Hct Level A	30x 2.5ml Ampules, 1x Value assignment sheet, 1x Insert	10311392 (570405) (04116087)
RAPIDQC Hct Level B	30x 2.5ml Ampules, 1x Value assignment sheet, 1x Insert	10311393 (570406) (06081574)
RAPIDQC Complete, Level 1	30x 2.5ml RAPIDQC Complete Level 1, 1x Value assignment sheet, 1x Insert	10309925 (02017464)
RAPIDQC Complete, Level 2	30x 2.5ml RAPIDQC Complete Level 2, 1x Value assignment sheet, 1x Insert	10309926 (07519905)
RAPIDQC Complete, Level 3	30x 2.5ml RAPIDQC Complete Level 3, 1x Value assignment sheet, 1x Insert	10309927 (07182730)

Appendix D: Interfacing to External Devices

The system has two data ports – Port 1 and Port 2 (*Figure 67*).

Figure 67: Left: Port 1 (Female), Right: Port 2 (Male)

Data Port 1 (Female)		Data Port 2 (Male)	
Pin 1	Not used	Pin 1	Not used
Pin 2	Tx data (transmitted)	Pin 2	Tx data (transmitted)
Pin 3	Rx data (received)	Pin 3	Rx data (received)
Pin 4	DTR (data terminal ready)	Pin 4	DTR (data terminal ready)
Pin 5	0V digital	Pin 5	0V digital
Pin 6	Not used	Pin 6	Not used
Pin 7	Not used	Pin 7	Not used
Pin 8	CTS (clear to send)	Pin 8	CTS (clear to send)
Pin 9	Not used	Pin 9	+5V digital

For details on interfacing to external devices, refer to the *RAPIDLab 348EX Interface Manual*.

The system supports 3 data communication protocols on Port 1. Port 2 supports only the LIS 1 protocol. For information about configuring the data ports, see *Changing Communication Options, page 170*.

LIS 1

LIS 1 allows communication to external printers or to data collection systems that accept asynchronous, unidirectional data transmission.

LIS 1Data Format (default)

Baud rate	9600
Start bit	1
Stop bit	1
Data bits	8
Parity	OFF

The transmitted data has the same format as the data sent to the internal printer.

LIS 2

LIS 2 allows communication to external data collection systems which accept asynchronous, unidirectional data in LIS 2 format.

LIS 2 Data Format (default)

Baud rate	9600
Start bit	1
Stop bit	1
Data bits	8
Parity	OFF

The transmitted data has the format and protocol defined in the *RAPIDLab 348EX Interface Manual*.

LIS 3

LIS 3 allows communication to HIS and LIS systems.

LIS 3 Data Format (default)

Baud rate	9600
Start bit	1
Stop bit	1
Data bits	8
Parity	OFF

The transmitted data has the format and protocol defined in the *RAPIDLab 348EX Interface Manual*.

Appendix E: References

This section lists the documents referred to in the rest of this guide.

1. Clinical and Laboratory Standards Institute. *Blood Gas and pH Analysis and Related Measurements*; Approved Guideline-Second Edition (includes CLSI/NCCLS C27-A). CLSI Document C46-A2. Wayne (PA): CLSI; 2009.
2. Douglas IHS, McKenzie PJ, Leadingham I, Smith G. Effect of halothane h. on pO_2 electrode. *Lancet* 1978: (Dec. 23 and 30).
3. Clinical and Laboratory Standards Institute. GP05-A3 (Electronic Document) *Clinical Laboratory Waste Management*. Wayne (PA): CLSI; 2011.
4. U.S. Dept. of Health and Human Services. Health Care Financing Administration Public Health Service. 42 CFR Part 405, Subpart K, *et al*, Federal Register: Clinical Improvement Amendments of 1988; Final Rule. Washington, D.C.: GPO, 1992.
5. Clinical and Laboratory Standards Institute. *Principles and Definitions; Approved Guideline - Second Edition*. CLSI Document C24-A2. Villanova (PA): CLSI; 1999.
6. Tietz NW ed. *Fundamentals of Clinical Chemistry*. 3rd ed. Philadelphia: WB Saunders, 1987; 864-891.
7. Eastham RD. *Biochemical Values in Clinical Medicine*. John Wright Ltd, 1985.
8. Richterich R, Colombo JP. *Clinical Chemistry: Theory, Practice and Interpretation*. John Wiley and Sons, 1981.
9. Borow M, *Fundamentals of Homeostasis*. 2nd ed. Medical Examination Publishing Co 1977.
10. Bold AM, Wilding P. *Clinical Chemistry: SI units with Adult Normal Reference Values*. Blackwell Scientific Publications, 1975.
11. Lentner C ed. *Geigy Scientific Tables, Vol. 3: Physical Chemistry Composition of Blood, Hematology Somatometric Data*. Vol 3, 8th ed. Basle: Ciba- Geigy Ltd., 1984; 82-83.
12. Mayne PD *et al*. *J Clin Pathol* 1984; 37: 859-861.
13. Urban P *et al*. *Clin Chem* 1985; 31/2: 264-266.

14. Clinical and Laboratory Standards Institute. *Protection of laboratory workers from occupationally acquired infections. 3rd ed*. CLSI Document M29-A3. Wayne (PA): CLSI; 2005.

15. Clinical and Laboratory Standards Institute. *Protection of laboratory workers from occupationally acquired infections. 3rd ed.* CLSI Document M29-A3. Wayne (PA): CLSI; 2005.

16. Siggaard-Anderson O. Electrochemistry. In: Tietz NW editor. *Fundamentals of Clinical Chemistry*. 3rd ed Philadelphia: WB Saunders, 1987. 87-100.

17. Siggaard-Anderson O, Durst RA, Maas AHJ. Physicochemical quantities and units in clinical chemistry with special emphasis on activities and activity coefficients. *Pure Appl Chem* 1984; 56: 567- 594.

18. Severinghaus JW, Bradley AF. Electrodes for blood pO_2 and pCO_2 determination. *J Appl Physiol* 1968; 13:515-520.

19. Clark LC Jr. Monitor and control of blood and tissue oxygen tensions. *Trans Am Soc Artif Intern Organs* 1956; 2: 41-56.

20. Shapiro BA, Harrison RA, Cane RD, Templin R. Clinical application of blood gases. 4th ed. Chicago: Year Book Medical Publishers, 1989. 270-272.

21. Fricke H. *Phys Rev* 1924; 24:575-587.

22. Barth E *et al*. Eur *J Clin Chem Clin Biochem* 1991; 29(4):281-292.

23. Moran R, Cormier A. The blood gases: pH, pO_2, pCO_2. *Clin Chem News* 1988; 14(4/5): 10-12.

24. Pagana KD, Pagana TJ. *Diagnostic testing and nursing implications: A Case Study Approach*. 3rd ed. St. Louis: CV Mosby, 1990. 448-449.

25. Mundy GR. Calcium homeostasis - the new horizons. In: Moran RF, editor. Ionized calcium: its determination and clinical usefulness. Proceedings of an international symposium. Galveston (TX): The Electrolyte/Blood Gas Division of the American Association for Clinical Chemistry, 1986: 1-4.

26. Ladenson JH. Clinical utility of ionized calcium. In: Moran RF, editor. Ionized calcium: its determination and clinical usefulness. Proceedings of an international symposium. Galveston (TX): The Electrolyte/Blood Gas Division of the American Association for Clinical Chemistry, 1986: 5-11.

27. Clinical Laboratory Standards Institute. *Definitions of quantities and conventions related to blood pH and gas analysis*. CLSI Document C12-A. Villanova (PA): CLSI; 1994.

28. VanSlyke DD, Cullen GE. Studies of acidosis 1. The bicarbonate concentration of blood plasma, its significance and its determination as a measure of acidosis. *J Biol Chem* 1917; 30:289-346.

29. Clinical Laboratory Standards Institute. *Fractional oxyhemoglobin, oxygen content and saturation, and related quantities in blood: terminology, measurement, and reporting; tentative standard*. CLSI Document C25-T. Villanova (PA): CLSI; 1992.

30. Martin L. Abbreviating the alveolar gas equation: an argument for simplicity. *Respir Care* 1985; 30(11):964-967.

31. Peris LV, Boix JH, Salom JV, Valentin V, *et al.* Clinical use of the arterial/alveolar oxygen tension ratio. *Crit Care Med* 1983; 11(11):888-891.

32. Burrit MF, Cormier AD, Maas AHJ, Moran RF, O'Connell KM. Methodology and clinical applications of ion-selective electrodes. Proceedings of an international symposium. Danvers (MA): The Electrolyte/Blood Gas Division of the American Association of Clinical Chemistry, 1987.

33. Lecky JH, Ominsky AJ. Postoperative respiratory management. *Chest* 1972; 62:50S-57S.

34. Horovitz JH *et al.* Pulmonary response to major injury. *Arch Surg* 1974; 108:349-355.

35. Cane R *et al.* The unreliability of oxygen tension based indices in reflecting intrapulmonary shunting in the critically ill. *Crit Care Med* 1988; 12:1243-1245.

36. Ciba Corning CBA focus discussions with intensive care specialists.

37. Moran RF, Bradley F. Blood gas systems - major determinants of performance. Laboratory Medicine 1981; 12 (6) 353-358.

38. Beetham R. A review of blood pH and blood gas analysis. *Ann Clin Biochem* 1982; 19: 198-213.

39. Vedda GL, Holbeck CC. Properties of commercially available control materials for *p*H, pCO_2 and pO_2. *Clin Chem* 1980; 26: 1366-7.

40. Weisberg HF. Acid-Base pathophysiology in the neonate and infant. *Annals of Clinical and Laboratory Science* 1982; 12(4)249.

41. Kirchoff JR, Wheeler JF, Lunte CE, Heineman WR. Electrochemistry: principles and measurements. In: Kaplan LA, Pesce AJ editors. *Clinical Chemistry: Theory, Analysis, and Correlation*. 2nd ed. St. Louis: CV Mosby, 1989. 213-227.

42. Thomas LJ. Algorithms for selected blood acid-base and blood gas calculations. *J Appl Physiol* 1972; 33:154-158.

43. Stott RAW *et al. Clin Chem* 1995; 41(2):306-311.

44. Bakerman S in *ABCs of Interpretive Laboratory Data*. 1984 2nd Ed; 225.

45. Davis RE. *Laboratory Practice*. 1983; 15(12): 1376-1378.

46. Burtis C. and Bruns D. *Tietz Fundamentals of Clinical Chemistry and Molecular Diagnostics*. Seventh Edition. St. Louis, MO: Elsevier Saunders; 2015.

47. Tietz NW. *Clinical Guide To Laboratory Tests.* Philadelphia, PA: Saunders; 1983.

48. Tietz NW. *Fundamentals of Clinical Chemistry*. Third Edition. Philadelphia, PA: Saunders; 1987.

49. Bakerman, *S. Bakerman's ABCs: ABC's of Interpretive Laboratory Data*. Fourth Edition. Interpretive Laboratory Data, Inc.; 2002.

50. Malley W. *Clinical blood gases: Application and Non-Invasive Alternatives.* Philadelphia, PA; Saunders; 1990.

51. Wu, A. *Tietz Clinical Guide To Laboratory Tests.* Fourth Edition. Philadelphia, PA: Saunders; 2006.

52. Meites, S. Editor-in-Chief. *Pediatrics Clinical Chemistry: Reference (Normal) Values.* Third Edition.AACC Press; Washington DC; 1989.

53. Tietz NW. *Textbook of Clinical Chemistry*. Third Edition. Philadelphia, PA: Saunders; 1986.

Appendix F: Specifications

This appendix contains system specifications, including measurement ranges, method comparisons, precision and recovery information, precision on controls, measurement time, heater temperature ranges, samples information, display and printer specifications, warm-up time, environmental conditions, power requirements, size and weight, and a reference to the reagents used.

Measurement Range

The measurement range specifies the range for the indicated measured parameters.

Note See *Measurement Range - Dialysis Fluid Mode,* page 221 for specifications for dialysis fluid mode.

Measured Parameters

Assay [Unit]	Measurement range [Unit]	Details / Remarks	Reportable Range* (unit)
pH	6.001–8.000	(10.0–997.7 nmol/L H^+)	6.061 – 7.976 10.568 – 868.96 nmol/L H^+
pCO_2	5.0–250.0 mmHg	(0.67–33.33 kPa)	6.7 – 218.1 mmHg
pO_2	0.0–749.0 mmHg	(0.00–99.86 kPa)	0.6 – 676.9 mmHg
Na^+	80–200 mmol/L		84 – 186 mmol/L
K^+	0.50–9.99 mmol/L		0.83 – 9.94 mmol/L
Ca^{++}	0.20–5.00 mmol/L		49 – 152 mmol/L
Cl^-	40–160 mmol/L		0.23 – 5.00 mmol/L
Hct	12–75%		15 – 72%
*p*Atm	400–825 mmHg	(53.3–110.0 kPa)	

*The Measurement range is the range the analyzer is capable of measuring and includes values outside the Reportable Range. The performance of the analyzer outside the Reportable range specified in this table has not been verified. Only results within the Reportable range should be reported.

Calculated Parameters

Parameter	Range	
$HCO_{3(act\ and\ std)}$	0.0–60.0 mmol/L	
BE (ecf and B)	±29.9 mmol/L	
$ctCO_2$	0.0–60.0 mmol/L	
O_2SAT	0.0–100.0%	
O_2CT	0.0–40.0 mL/dL	
pO_2(A-a)	0.0–749.0 mmHg	(00–99.86 kPa)
pO_2(a/A)	0.00–1.00	
AnGap	±60.0 mmol/L	
*c*tHb(est)	2.0–25.0 g/dL	(20–250 g/L, 1.2–15.5 mmol/L)
Ca^{++}(7.4)	0.20–5.00 mmol/L	
pO_2/F_IO_2	0.00–5.00	

Limit of Quantitation

Altered low level whole blood samples were run across three lots, minimum of 3 replicates, on three RAPIDLab 348EXs. Each Analyzer was dedicated to a specific lot of reagent. Samples that overlapped the low end of the measuring interval were used for analysis of Limit of Quantitation for every analyte.

Parameter	Limit of Quantitation
pO_2	0.6 mmHg
pCO_2	6.7 mmHg
pH	10.6 nmol/L*
Na^+	84 mmol/L
K^+	0.83 mmol/L
Cl^-	49 mmol/L
Ca^{++}	0.23 mmol/L
Hct	15%

*pH= -log[H^+]= log1/([H^+]). For more information, refer to section *pH,* page 238.

RAPIDLab 348EX Parameter Linearity

All parameters on RAPIDLab 348EX systems are linear within the tested range as determined by following EP06-A:2003.

For pO_2 by amperometric technology, the method has been demonstrated to be linear from 28.4 – 676.9 mmHg with deviations from linearity within ± 5 up to 100mmHg; 5% > 100 mmHg.

For pCO_2 by a method described by Severinghaus and Bradley, the method has been demonstrated to be linear from 5.9 – 218.1 mmHg with deviations from linearity within ± 5 mmHg or ± 8%.

For pH by ISE technology, the method has been demonstrated to be linear from 6.071 – 7.969 Unit with deviations from linearity within ± 0.04.

For Na^+ by ISE technology, the method has been demonstrated to be linear from 88 – 189 mmol/L with deviations from linearity within ± 4 mmol/L.

For K^+ by ISE technology, the method has been demonstrated to be linear 0.76 – 9.94 mmol/L with deviations from linearity within ± 0.5 mmol/L.

For Cl^- by ISE technology, the method has been demonstrated to be linear 59 – 152 mmol/L with deviations from linearity within ± 5%.

For Ca^{++} by ISE technology, the method has been demonstrated to be 0.29 – 4.98 mmol/L with deviations from linearity within ± 0.05 mmol/L.

For Hct by conductivity technology, the method has been demonstrated to be 17 – 72% within the allowable nonlinearity in this interval.

Sensitivity of ISE Sensors

The analytical sensitivity (aka Slope) of the RL348EX ISE sensors is governed by the Nernst equation and determined by dividing the millivolt signal delta observed between two calibration solutions by the logarithmic difference in analyte concentration for the same two calibrator solutions. For more detailed information on the Nernst equation, *Appendix H, Operating Principles*

Typical analytical sensitivities for the RL348EX sensors are shown below along with allowable limits.

RL348EX Analytical Sensitivity

Analyte	Signal delta (6.8 Buffer - 7.3 Buffer)	Concentration delta Log (6.8 Buffer ÷ 7.3 Buffer)	Analytical Sensitivity (mV/dec)	Lower Analytical Sensitivity Action Limit (mV/dec)	Upper Analytical Sensitivity Action Limit (mV/dec)
pH	30 mV	-0.5000	-60.0	-54.0	-70.0
Na^+	-6 mV	-0.1047	57.3	45.8	64.9
K^+	17 mV	0.3010	56.5	53.2	64.8
Ca^{++}	9.3 mV	0.3010	30.9	21.9	33.9
Cl^-	9.7 mV	-0.1549	-62.6	-42.6	-68.4

Where:
Signal delta = millivolt difference between the 2 calibration solutions
Concentration delta = logarithmic difference in analyte concentrations between the 2 calibration solutions
Analytical Sensitivity, mV/dec = millivolts per decade change in analyte concentration

RAPIDLab 348EX Interfering Substances

The following table illustrates whether substances listed interfere with the specified analyte measurements at the concentrations indicated in the substance column.

Substance	Analyte	Effect
Acetaminophen (at 20 mg/dL)	pH	No
Acetaminophen (at 2 mg/dL)	Na^+,Ca^{++}, Cl^-	No
Salicylic Acid (at 20 mg/dL)	pH, Ca^{++}, Cl^-	No
Acetylsalicylic acid (at 50 mg/dL)	Ca^{++}, Cl^-	No
Ibuprofen (at 40 mg/dL)	Ca^{++}	No
Sodium Pentothal (at 300 mg/dL)	Ca^{++}, Cl^-, pH and K^+	No

Limitations

- Thiocyanate, Bromide or Iodide may interfere with Cl^-
- Abnormal protein levels may interfere with Hct
- Halothane and Nitrous Oxide may interfere with pO_2

- Salicylic acid concentrations > 30mg/dL and Teriflunomide concentrations > 30µg/mL demonstrate a negative interference with Ca^{++}

Irenat Interference

Irenat (Sodium Percholorate) can falsely lower ionized calcium results. We recommend the following preventive actions:

- Measure Ca^{++} before administering Irenat.
- Do not measure Ca^{++} while the patient is on Irenat.
- Ca^{++} may be measured 96 hours after the last dose of Irenat.

Method Comparison

A comparison of whole blood samples run on 6 RAPIDLab 348 systems was performed. The comparison was run against the RAPIDLab 248 analyzer for pH, tonometered blood for pCO_2 and pO_2, the 480 flame photometer for Na^+ and K^+, the 634 ISE analyzer for Ca^{++}, the 925 chloride meter for Cl^- and the Hawksley Microcentrifuge for Hct.

The comparison was repeated for micro sample mode.

In the following tables, the linear regression analysis equation is y = mx + b, and C of C is the coefficient of correlation. The letter M precedes instrument model numbers.

Note All performance data presented in this section was generated using RAPIDLab 348 systems. In respect to performance characteristics, the RAPIDLab 348EX system is statistically equivalent to the RAPIDLab 348 system. The data below represents the performance of both the RAPIDLab 348 system and the RAPIDLab 348EX system.

pH

n	180
Range	7.000–7.680 (H^+ 15.8–100.0 nmol/L)
Equation	M348 = M248 x 0.999 + 0.007
C of C	1.000

pCO_2

n	180
Range	14.2–149.3 mmHg (1.89–19.91 kPa)

Equation	M348 = tonometry x 0.999 - 0.356
C of C	0.999

pO_2

n	180
Range	28.3–372.6 mmHg (3.77–49.68 kPa)
Equation	M348 = tonometry x 0.986 +1.731
C of C	0.999

Na^+

n	180
Range	85–172 mmol/L
Equation	M348 = M480 x 0.996 - 1.070
C of C	0.998

K^+

n	180
Range	2.42–7.05 mmol/L
Equation	M348 = M480 x 1.013 - 0.086
C of C	0.999

Ca^{++}

n	90
Range	0.69–3.10 mmol/L
Equation	M348 = M634 x 0.982 - 0.001
C of C	0.999

Cl^-

n	90
Range	57–130 mmol/L
Equation	M348 = M925 x 1.045 - 4.602
C of C	0.998

Hct

n	136
Range	12–60%
Equation	M348 = microcentrifuge x 1.008 - 0.331
C of C	0.994

Micro Sample Mode

pH

n	270
Range	6.986–7.707 (H^+ 19.6–103.3 nmol/L)
Equation	M348 = M248 x 1.021 - 0.129
C of C	0.998

pCO_2

n	270
Range	14.1–150.4 mmHg (1.88–20.05 kPa)
Equation	M348 = tonometry x 1.014 - 2.564
C of C	0.998

pO_2

n	270
Range	28.3–493.5 mmHg (3.77–65.79 kPa)
Equation	M348 = tonometry x 1.022 - 8.451
C of C	0.998

Na^+

n	360
Range	122–172 mmol/L
Equation	M348 = M480 x 1.044 - 7.485
C of C	0.991

K^+

n	360
Range	2.31–7.64 mmol/L

Equation	M348 = M480 x 0.997 - 0.026
C of C	0.995

Ca^{++}

n	180
Range	0.24–4.04 mmol/L
Equation	M348 = M634 x 0.978 - 0.017
C of C	0.993

Cl^{-}

n	180
Range	83–131 mmol/L
Equation	M348 = M925 x 1.037 - 3.749
C of C	0.978

Hct

n	156
Range	12–60%
Equation	M348 = microcentrifuge x 1.036 - 1.672
C of C	0.999

Method Comparison - RL348EX Blood Gas

A total of n=475 whole blood samples were presented to all n=4 M348 and n=4 348EX.

This testing showed, for all analytes, no instances where the mean 348EX analyzer results exhibited non-equivalency, in terms of Deming regression, to the existing mean M348 Blood Gas Analyzer results with slope values obtained all being within the specification of $0.90 < m < 1.10$ and R^2 criteria of > 0.95.

Analyte	n	Range	Units	Equation	R^2
pH	475	6.720–7.607		348EX = 348 x 0.997 + 0.018	0.999
pCO_2	475	6.225–230.3	mmHg	348EX = 348 x 0.964 - 0.058	0.999
pO_2	475	28.0–688.6	mmHg	348EX = 348 x 1.012 + 1.138	0.999
Na^+	475	89–183	mmol/L	348EX = 348 x 1.001 - 0.524	0.997
K^+	475	1.78–8.61	mmol/L	348EX = 348 x 1.012 - 0.066	0.998
Ca^{++}	475	0.52–4.69	mmol/L	348EX = 348 x 0.995 - 0.014	0.998

Analyte	n	Range	Units	Equation	R^2
Cl^-	475	60–144	mmol/L	348EX = 348 x 1.038 - 3.737	0.986
Hct	475	12–75	%	348EX = 348 x 1.019 - 0.829	0.997

Method Comparison - RL348EX Dialysis Fluid

Analyte	n	Range	Units	Equation	R^2
Na^+	38	100 –185	mmol/L	348EX = 348 x 0.981 + 2.144	0.999
K^+	38	0.7–8.0	mmol/L	348EX = 348 x 1.001 - 0.004	1.000
Ca^{++}	38	0.25–4.1	mmol/L	348EX = 348 x 1.009 - 0.048	0.999

Precision and Recovery on Whole Blood

Whole blood was tonometered at 37°C for pH, pCO_2 and pO_2 analysis for 6 levels, and spiked/diluted for Na^+, K^+, Ca^{++}, Cl^- and Hct analysis for 6 levels, and run on 4 RAPIDLab 348EX systems. In the tables that follow, WRSD means within-run standard deviation.

Level 1

Analyte		n	WRSD	Expected	Observed	%Recovery	%CV
pH		10	0.004	7.026	7.023	100.0	0.06
H^+	nmol/L	10	0.966	94.2	94.9	100.7	1.02
pCO_2	mmHg	10	0.146	20.5	20.9	102.0	0.70
pCO_2	kPa	10	0.020	2.73	2.78	102.0	0.70
pO_2	mmHg	10	0.258	48.6	49.3	101.5	0.52
pO_2	kPa	10	0.034	6.48	6.58	101.5	0.52
Na^+	mmol/L	10	0.734	109	108	99.0	0.68
K^+	mmol/L	10	0.023	3.22	3.19	98.9	0.72
Ca^{++}	mmol/L	10	0.006	1.08	1.04	96.0	0.58
Cl^-	mmol/L	10	0.550	68	67	98.9	0.82
Hct	%	10	0.392	28	30	105.2	1.32

Level 2

Analyte		n	WRSD	Expected	Observed	%Recovery	%CV
pH		10	0.003	7.112	7.111	100.0	0.04
H^+	nmol/L	10	0.489	77.2	77.5	100.3	0.63
pCO_2	mmHg	10	1.938	33.6	34.3	102.1	5.66
pCO_2	kPa	10	0.258	4.48	4.57	102.1	5.66
pO_2	mmHg	10	0.447	84.7	85.3	100.7	0.52
pO_2	kPa	10	0.060	11.30	11.38	100.7	0.52
Na^+	mmol/L	10	0.584	126	124	99.1	0.47
K^+	mmol/L	10	0.026	3.64	3.62	99.3	0.71
Ca^{++}	mmol/L	10	0.013	1.27	1.23	97.0	1.08
Cl^-	mmol/L	10	0.753	90	90	99.9	0.84
Hct	%	10	0.329	32	33	103.3	0.99

Level 3

Analyte		n	WRSD	Expected	Observed	%Recovery	%CV
pH		10	0.010	7.234	7.231	100.0	0.13
H^+	nmol/L	10	1.295	58.4	58.7	100.5	2.21
pCO_2	mmHg	10	0.485	46.0	47.0	102.1	1.03
pCO_2	kPa	10	0.065	6.14	6.26	102.1	1.03
pO_2	mmHg	10	0.688	106.7	107.3	100.6	0.64
pO_2	kPa	10	0.092	14.23	14.31	100.6	0.64
Na^+	mmol/L	10	0.240	134	133	99.9	0.18
K^+	mmol/L	10	0.030	4.18	4.14	99.1	0.72
Ca^{++}	mmol/L	10	0.007	1.29	1.28	98.7	0.56
Cl^-	mmol/L	10	1.156	96	97	100.9	1.19
Hct	%	10	0.460	39	39	100.9	1.18

Level 4

Analyte		n	WRSD	Expected	Observed	%Recovery	%CV
pH		10	0.013	7.372	7.370	100.0	0.17
H^+	nmol/L	10	1.255	42.5	42.7	100.6	2.94
pCO_2	mmHg	10	0.769	68.3	69.8	102.3	1.10
pCO_2	kPa	10	0.102	9.10	9.31	102.3	1.10
pO_2	mmHg	10	1.349	152.7	153.7	100.6	0.88
pO_2	kPa	10	0.180	20.36	20.49	100.6	0.88
Na^+	mmol/L	10	0.316	140	141	100.3	0.22
K^+	mmol/L	10	0.036	5.94	5.95	100.1	0.61
Ca^{++}	mmol/L	10	0.014	1.44	1.44	100.1	0.97
Cl^-	mmol/L	10	0.943	100	101	100.9	0.94
Hct	%	10	0.627	52	53	100.7	1.19

Level 5

Analyte		n	WRSD	Expected	Observed	%Recovery	%CV
pH		10	0.004	7.446	7.447	100.0	0.06
H^+	nmol/L	10	0.353	35.8	35.7	99.7	0.99
pCO_2	mmHg	10	0.763	99.9	100.7	100.8	0.76
pCO_2	kPa	10	0.102	13.32	13.43	100.8	0.76
pO_2	mmHg	10	1.762	198.6	199.7	100.6	0.88
pO_2	kPa	10	0.235	26.48	26.63	100.6	0.88
Na^+	mmol/L	10	0.409	150	149	99.4	0.28
K^+	mmol/L	10	0.053	6.98	7.03	100.8	0.75
Ca^{++}	mmol/L	10	0.012	1.71	1.69	98.9	0.68
Cl^-	mmol/L	10	0.516	110	110	100.0	0.47
Hct	%	10	0.418	61	62	100.6	0.68

Level 6

Analyte		n	WRSD	Expected	Observed	%Recovery	%CV
pH		10	0.009	7.568	7.565	100.0	0.12
H^+	nmol/L	10	0.573	27.0	27.2	100.7	2.11
pCO_2	mmHg	10	1.314	135.1	136.4	101.0	0.96
pCO_2	kPa	10	0.175	18.01	18.18	101.0	0.96
pO_2	mmHg	10	5.237	385.0	389.3	101.1	1.35
pO_2	kPa	10	0.698	51.34	51.90	101.1	1.35
Na^+	mmol/L	10	0.654	169	168	99.4	0.39
K^+	mmol/L	10	0.042	7.61	7.62	100.1	0.55
Ca^{++}	mmol/L	10	0.027	2.20	2.17	98.3	1.23
Cl^-	mmol/L	10	1.719	135	137	101.4	1.26
Hct	%	10	0.303	73	73	101.0	0.41

Precision on Controls

Data was collected across 4 RAPIDLab 348EX systems over 20 days. In the following tables, Total SD means total standard deviation.

pH

Level	n	Mean	Total SD	%CV
1	160	7.125	0.003	0.05
2	160	7.386	0.003	0.04
3	160	7.581	0.003	0.04

H^+ (nmol/L)

Level	n	Mean	Total SD	%CV
1	160	74.9	0.6	0.78
2	160	41.1	0.3	0.75
3	160	26.3	0.2	0.67

pCO_2 (mmHg)

Level	n	Mean	Total SD	%CV
1	160	73.9	0.7	0.97
2	160	44.5	0.4	0.84
3	160	23.6	1.4	6.00

pCO_2 (kPa)

Level	n	Mean	Total SD	%CV
1	160	9.9	0.1	0.97
2	160	5.9	0.0	0.84
3	160	3.2	0.2	6.00

pO_2 (mmHg)

Level	n	Mean	Total SD	%CV
1	160	55.3	0.7	1.36
2	160	93.3	0.7	0.71
3	160	144.0	1.5	1.01

pO_2 (kPa)

Level	n	Mean	Total SD	%CV
1	160	7.4	0.1	1.36
2	160	12.4	0.1	0.71
3	160	19.2	0.2	1.01

Na^+ (mmol/L)

Level	n	Mean	Total SD	%CV
1	160	119.2	1.1	0.92
2	160	140.9	0.7	0.48
3	160	159.7	0.7	0.42

K^+ (mmol/L)

Level	n	Mean	Total SD	%CV
1	160	3.05	0.01	0.30
2	160	4.97	0.02	0.47
3	160	7.06	0.05	0.72

Ca^{++} (mmol/L)

Level	n	Mean	Total SD	%CV
1	80	1.66	0.03	1.74
2	80	1.25	0.01	0.89
3	80	0.76	0.02	2.06

Cl^- (mmol/L)

Level	n	Mean	Total SD	%CV
1	80	86.4	1.0	1.19
2	80	109.3	1.3	1.19
3	80	127.7	1.6	1.22

Hct (%)

For Hct, data was collected from 5 runs across 4 RAPIDLab348EX systems over 20 days.

Level	n	Mean	Total SD	%CV
1	64	14.0	1.0	6.9
2	160	26.5	0.6	2.4
3	160	48.6	0.7	1.4
4	64	65.0	0.8	1.2

Note Hct levels 1 and 4 analyzed in syringe mode as CVM.

Reproducibility results following CLSI EP05 Guidelines on one lot of RAPIDQC Complete run over 5 days, 1 run per day, 5 replicates per run across the 3 locations.

RAPIDQC Precision

Parameter	Sample	Mean	n	Repeatability		Between-Day		Between-Site		Reproducibility	
				SD	%CV	SD	%CV	SD	%CV	SD	%CV
pO_2 (mmHg)	Level 1	137.4	75	2.18	1.60%	1.53	1.10%	0	0.00%	2.66	1.90%
	Level 2	87.8	75	1.37	1.60%	0.96	1.10%	0.39	0.40%	1.72	2.00%
	Level 3	20.3	75	1.11	5.50%	0.28	1.40%	1.22	6.00%	1.67	8.20%
pCO_2 (mmHg)	Level 1	74.5	75	1.03	1.40%	0.2	0.30%	0.46	0.60%	1.14	1.50%
	Level 2	43.6	75	0.62	1.40%	0.33	0.80%	0.3	0.70%	0.77	1.80%
	Level 3	25.6	75	0.19	0.70%	0.16	0.60%	0.3	1.20%	0.39	1.50%
pH	Level 1	7.123	75	0.002	0.00%	0.002	0.00%	0.0031	0.00%	0.0043	0.10%
	Level 2	7.321	75	0.0016	0.00%	0.004	0.00%	0.0039	0.10%	0.0055	0.10%
	Level 3	7.498	75	0.0024	0.00%	0.002	0.00%	0.0032	0.00%	0.0047	0.10%
Na^+ (mmol/L)	Level 1	116.7	75	0.33	0.30%	0.35	0.30%	0.36	0.30%	0.6	0.50%
	Level 2	137.2	75	0.4	0.30%	0.41	0.30%	0.51	0.40%	0.77	0.60%
	Level 3	159.2	75	0.32	0.20%	0.55	0.30%	0.13	0.10%	0.64	0.40%
K^+ (mmol/L)	Level 1	3.39	75	0.026	0.80%	0.022	0.60%	0	0.00%	0.034	1.00%
	Level 2	5.26	75	0.033	0.60%	0.051	1.00%	0	0.00%	0.061	1.20%
	Level 3	6.81	75	0.035	0.50%	0.078	1.10%	0	0.00%	0.086	1.30%
Ca^{++} (mmol/L)	Level 1	1.72	75	0.012	0.70%	0.016	0.90%	0.015	0.90%	0.025	1.40%
	Level 2	1.38	75	0.01	0.70%	0.017	1.20%	0.013	0.90%	0.023	1.70%
	Level 3	0.9	75	0.006	0.70%	0.01	1.10%	0.01	1.10%	0.015	1.70%
Cl^- (mmol/L)	Level 1	83	75	0.6	0.70%	0.6	0.70%	0.2	0.20%	0.8	1.00%
	Level 2	104	75	0.9	0.90%	1	1.00%	0.9	0.80%	1.6	1.50%
	Level 3	124	75	1.3	1.00%	2.1	1.70%	0	0.00%	2.5	2.00%

Precision results following CLSI EP05 Guidelines on one lot of CVM® Hct, run over 20 days, 2 runs per day, 2 replicates per run across 3 instruments each containing a different Hct sensor lot.

CVM Hct Precision

Parameter	Sample	Mean	n	Repeatability		Between-Day		Between-Instr.		Reproducibility	
				SD	%CV	SD	%CV	SD	%CV	SD	%CV
Hct (%)	Level 1	15.2	218	0.6	3.70%	0	0.30%	0	0.00%	0.9	5.70%
	Level 2	24.4	215	0.7	2.90%	0	0.00%	0	0.00%	1	4.00%
	Level 3	43.9	214	0.7	1.70%	0.6	1.40%	0.1	0.30%	1.1	2.40%
	Level 4	65.1	210	1.6	2.40%	0.8	1.20%	0.5	0.80%	1.8	2.80%

348 Slope/Calibration Standards

Parameter	348 Slope/ Calibration
pH	Disodium Hydrogen Orthophosphate (SRM 186-II-G)
pH	Potassium Dihydrogen Orthophosphate (SRM 186-I-G)
Ca	Calcium Carbonate (SRM 915b)
Na/Cl	Sodium Chloride (SRM 919b)
K	Potassium Chloride (SRM 918a)
Hct	Sodium Chloride (SRM 919b)[a]

a. Hct calibrator values are traceable through NIST SRM 919b using an analar solution confirmed to be 120mM Na^+ by flame photometry and measured on a conductivity meter following a validated SOP targeting 3.43mS/cm.

Measurement Time

Results are displayed within 45 to 90 seconds of returning the probe (typically less than 60 seconds).

Heater

The sensor operating temperature is 37.0°C ± 0.15°C.

The pre-heater temperature is 37°C ± 1°C.

Samples

For information about collecting, storing, and handling of samples, see *Section 6, Handling Samples and Reagents*. In addition, observe the following precautions:

- Use whole blood, properly collected.
- Ensure that the sample is free from hemolysis
- Store any samples that are not analyzed immediately according to the procedures in *Section 6, Handling Samples and Reagents*.
- You can analyze fresh samples at a temperature of up to 40°C.
- We recommend using Siemens QC material and Siemens Calibration verification material.

Sample Volume

95 µL (syringe/capillary) nominal, 50 µL (micro capillary sample).

Display and Printer

Display

VGA 640 x 480 color touch screen display.

Printer

32-character thermal printer.

Environmental Conditions

Operation

Temperature range	15–32°C
Ambient operating relative humidity	5–85%, non-condensing
Maximum relative humidity	85% at 32°C, non-condensing
Barometric pressure range	400–825 mmHg
Maximum ambient light	8000 lux

Transportation

Temperature range	4°C–37°C
Maximum relative humidity	95% at 37°C

Storage

Temperature range	4°C–25°C
Maximum relative humidity	95% at 25°C

Power Requirements

Power rating	80VA
Voltage	100–240 VAC, 50/60 Hz
Leakage current	< 0.5 mA

Size

With Barcode Reader

Width	50.0 cm (19.6 inches)
Depth	35.3 cm (13.9 inches)
Height	38.2 cm (15.0 inches)
Weight	9.8 kg (21.6 lb) system only
	12.2 kg (26.9 lb) system + reagents and gas

Without Barcode Reader

Width	38.5 cm (15.2 inches)
Depth	35.3 cm (13.9 inches)
Height	38.2 cm (15.0 inches)

Weight	9.4 kg (20.7 lb) system only
	11.8 kg (26.0 lb) system + reagents and gas

Reagents

See *Appendix H, Operating Principles* for a complete list of reagents for use with the system. Store solutions at 4–25°C, away from direct sunlight.

Measurement Range - Dialysis Fluid Mode

Measured Parameters - Dialysis Fluid Mode

The dialysate fluid used in hemodialysis is an aqueous non-IVD solution mixed from concentrates. The dialysate measurement tests dialysate solution concentrations prior to performing dialysis. The utility of such analysis is to verify the correct dilution of a hemodialysis concentrate before clinical application. In dialysis fluid mode, the system directly measures the following parameters on acetate or bicarbonate-based renal fluid dialysates; that is, after dilution from the associated dialysis fluid concentrate.

Note All performance data on dialysis fluid for sodium and potassium presented in this section was generated using RAPIDLab 348 systems. In respect to the performance characteristics, the RAPIDLab 348EX system is statistically equivalent to the RAPIDLab 348 system, therefore the performance data is representative of the RAPIDLab 348EX system. The performance data generated for ionized calcium on dialysis fluid was performed on the RAPIDLab 348EX system only.

Parameter	Units	Measurement Range	Resolution
pH	pH	6.001–8.000	0.001
H^+	nmol/L	10.0–997.7	0.1
pCO_2	mmHg	5.0–250.0	0.1
	kPa	0.67–33.33	0.01
Na^+	mmol/L	80–200	1
K^+	mmol/L	0.50–9.99	0.01
Ca^{++}	mmol/L	0.20–5.00	0.01

Calculated Parameters - Dialysis Fluid Mode

The following parameters are calculated, not directly measured.

Parameter	Units	Measurement Range	Resolution
Actual bicarbonate	mmol/L	0.0–60.0	0.1
*c*tCO_2	mmol/L	0.0–60.0	0.1

Accuracy on Measured Parameters - Dialysis Fluid Mode

Na^+	Mean difference from reference method (flame photometry)	±2 mmol/L
K^+	Mean difference from reference method (flame photometry)	±0.1 mmol/L
pH	This value is provided only for indication	
pCO_2	This value is provided only for indication	
Ca^{++}	This value is provided only for indication	

Within-run Precision - Dialysis Fluid Mode

Na^+	CV is 1% typical (1.5% at 95% confidence interval)
K^+	CV is 1% typical (1.5% at 95% confidence interval)

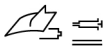
Sample Size - Dialysis Fluid Mode

Dialysis fluid sample size is nominally 240 µL.

Appendix G: Symbols

This appendix lists the symbols displayed on the system and system packaging and the meaning of each symbol.

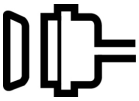
System and Packaging

Symbol	Description
	Shows the probe lever position for sampling from syringes and capillaries.
	Shows the probe lever position for sampling from ampules and other open top containers.
	Cautions you not to spray this area with cleaning solutions or other fluids that may damage sensitive parts of the system.
	Shows the direction of rotation of the pump.
	Cautions you about the risk of exposure to potential electrical hazards.
	Alerts you to important information about the fuses.
	Indicates that the input electricity is alternating current.
	Alerts you to important information about gas bottle pressure.
	Indicates the instrument ground test point (earth terminal).

Symbol	Description
	• In this manual, this symbol is used for both Warnings and Cautions. A WARNING indicates the risk of personal injury or loss of life if operating procedures and practices are not correctly followed. A CAUTION indicates the possibility of loss of data or damage to or destruction of equipment if operating procedures and practices are not strictly observed. • On the touch screen, this symbol indicates that action is required.
	Indicates that this equipment is classified as Waste Electrical and Electronic Equipment under the European WEEE Directive. It must be recycled or disposed of in accordance with applicable local requirements.
	Indicates that the analyzer is classed as IEC Type B equipment (Class 1 equipment providing an adequate degree of protection against electric shocks particularly regarding allowable leakage currents and reliability of the protective earth connection).
	The RL348EX instrument has been tested for safety by TÜV SÜD, a national certification body, for conformity to global markets, including Canada, US, and Europe.
	CE Mark (+notified body ID#) TÜV Rheinland LGA Products GmbH
	Indicates an *in vitro* diagnostic medical device.
	Manufacturer.

Symbol	Description
	Date of manufacture.
	Authorized Representative.
	Catalog Number.
	Cautions you about the risk of exposure to biohazards.
	Identifies the location of the USB ports.
	Advises you to consult the operating instructions to obtain information needed for the proper use of the instrument.
	Shows the area in which the date can be written in pencil.
	Fragile, handle with care.
	Temperature limitation (4°–25°C).
	Keep dry.
	Keep away from sunlight and heat.
	Sterile.
	Batch code.
	Serial number.

Symbol	Description
	Use by date.
	Control.
	Indicates maximum fill level.
	Do not re-use.
	Cautions you that this is a heavy object that requires assistance to lift.
	Do not stack.
	Do not use if package is damaged.
	Keep this way up.
	Please recycle this packaging.
	Printed on recycled materials.
	Device for near patient testing.
	Indicates compliance with Green Dot packaging standards.
	Indicates compliance with RESY packaging standards.

Symbol	Description
	This system contains certain toxic or hazardous substances or elements. The environmental protection use period for this system is 50 years. The system can be used safely during its environmental protection use period. The system should be recycled immediately after its environmental protection use period has expired.
	This symbol identifies a hazardous area on the equipment.
	This symbol identifies the location of a power connector (power cord).
	This symbol identifies the location of a serial port.
	This symbol identifies the location of the USB port.
	This symbol identifies the Laboratory Information System.
	This symbol identifies that this electronic information product does not contain any toxic or hazardous substances or elements, and is green and environmental. This system can be recycled after being discarded, and should not be casually discarded.
	This symbol identifies the system power button

User Interface

This section describes the symbols that display on the system user interface.

Symbol	Action	Description
	Back	Select this button to exit the current screen without saving and change the display back to the previous screen in the series.
	Next	Select this button to display the next screen in the series.
	Up	Select this button to display the previous result or entry.
	Down	Select this button to display the next result or entry.
	System Busy	This symbol indicates that the system is busy or that a timer is counting down.
	Select syringe sample	Select this button to perform a syringe sample test.
	Select capillary sample	Select this button to perform a capillary sample test.
	Quality Control	Select this button to perform a Quality Control (QC) test.
	Select DF sample	Select this button to perform a Dialysis Fluid (DF) sample test.
	Settings	Select this button to configure system settings.
	Beep On	Toggles the audible beep signal on.
	Beep Off	Toggles the audible beep signal off.

Appendix H: Operating Principles

The system measurement technology is based on electrochemistry. Electrochemistry is the measurement of current, or voltage, occurring in an electrochemical cell, between a chemical and an electrical system.

Each electrode, or sensor, is designed to selectively measure the concentration of a specific substance. Many elements in a sample may interact with a sensor, but the sensor is highly selective for one substance over others. The hematocrit sensor measures the conductance of the sample, and the Hct % is calculated from this value.

The potential generated at the sensor is converted into an electronic signal by a transducer mechanism. The system uses potentiometry, amperometry and conductivity. Potentiometry measures the potential that develops at the sensor. Amperometry and conductivity involve applying a voltage to the sensor and then measuring the current generated.

The electronic signal is filtered and smoothed, and converted into a concentration measurement expressed in standard units.

Potentiometry

During sample analysis, a potential develops at the sensor as a result of the interaction with the analyte (ion). The potential is related to the amount of analyte in the sample.

The reference sensor provides a fixed potential, which is independent of analyte activity, and is used to compare the measured potential.

The sensor potential corresponds to the analyte activity, and is directly related of the concentration of the analyte in solution. The potential is expressed by the Nernst equation:

$$E_{cell} = K + (2.3RT/ZF) \log a_i$$

where:

- E_{cell} = electrochemical cell potential
- K = a constant (produced by various sources such as the liquid junction)
- R = gas constant
- T = absolute temperature
- Z = ionic charge

F = Faraday's constant

a_i = activity of the ion in the sample

This equation shows that the potential is logarithmically related to the activity of the analyte in the sample.

However, the sensor actually measures the activity of the analyte in solution. In clinical chemistry results are typically expressed as concentration rather than activity. The activity of an ion is equivalent to the concentration (mol/L) multiplied by the activity coefficient (the degree with which the ion interacts with other ions in solution). The activity coefficient depends on the ionic strength of the solution, and generally decreases with increasing ionic strength.[16]

Using an established convention, the activity of ions as measured by the sensors can be expressed as concentration. Ionic strength is the primary variable affecting the activity coefficient of ions in solution. The normal ionic strength of blood plasma water is 160 mmol/kg.[17]

Controlling the ionic strength of calibrating solutions to 160 mmol/kg sets the activity coefficients of ionic species in the calibrations equal to those of blood plasma water at ionic strengths close to normal. Both calibrations and measurements may then be expressed in units of concentration rather than activity.

Amperometry

Amperometry is an electrochemical technique used to determine the amount of analyte in solution by applying a fixed voltage between two electrodes in an electrochemical cell, then measuring the current flowing.

The measuring electrode is negatively charged and serves as a cathode in the electrical system. The reference electrode is positively charged, and serves as the anode. Both electrodes are attached to an external voltage source.

As the sample comes into contact with the two electrodes, a known voltage is applied to the cathode. This voltage attracts molecules from the analyte in solution to the cathode causing a chemical reaction (reduction) that uses electrons. The electrons are replaced immediately in the sample solution by a separate reaction (oxidation) that takes place at the anode. The two reactions result in a current flow that can be measured. The current measured is directly proportional to the concentration of analyte (reacting at the cathode) present in the sample.

Conductivity

Conductivity is a non specific measurement of a solution's ability to pass current. A fixed alternating voltage is applied via a known resistance to the outer terminals of a 4 pole sensor. The voltage difference between the two inner terminals and the outer terminals is measured.

Conductance is the reciprocal of resistance, and Ohm's Law states that:

resistance = applied voltage / current flowing

therefore:

conductance = current flowing / applied voltage

The conductivity (C) in a cell is given by the equation:

$C = A / GL$

where:

A = the cross-sectional area of the cell
L = the distance between the terminals of the cell, and
G = the conductance measured

Sensors

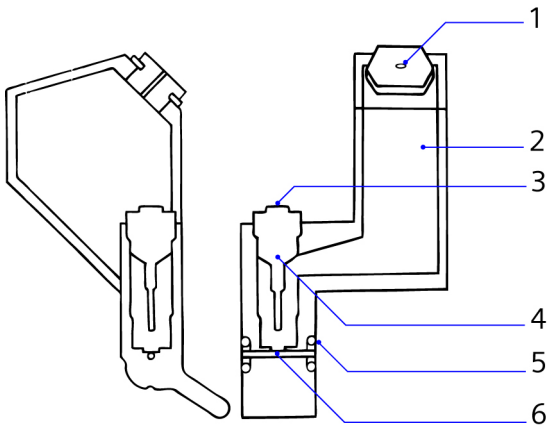
Reference Sensor

The reference sensor contains a silver (Ag) wire, coated with a layer of silver chloride (AgCl) surrounded by a saturated potassium chloride (KCl) solution. By making sure that the concentration of chloride ions (Cl^-) remains unchanged in the solution, the reference sensor maintains a constant electrical potential. KCl is added to the reference sensor solution chamber to maintain a saturated solution of KCl at 37°C.

A permeable cellulose membrane separates the KCl solution from the sample. During analysis a diffusion potential, created between the sample and KCl solution, provides the fixed half-cell potential required for measurement.

The Ag wire conducts the potential to the measurement device where it is compared to the potential of the measuring sensor. The potential difference measured reflects the concentration of analyte in the sample.

Figure 68: Reference Sensor (cutaway view)



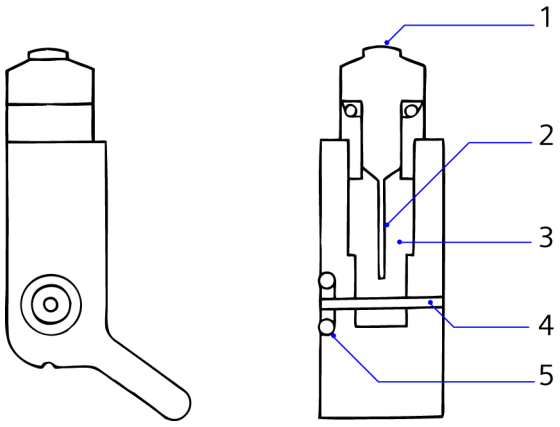
1. Fill Cap
2. Fill Solution
3. Sensor Contact
4. Inner electrode (Ag/AgCl wire)
5. O-rings
6. Sample path

pH Sensor

The pH sensor is based on ISE technology and is a half-cell that forms a complete cell with the external reference sensor. It contains a silver/silver chloride wire (Ag/AgCl) surrounded by a buffer solution of fixed hydrogen ion concentration. A glass membrane, highly sensitive and specific for hydrogen ions, separates the sample from the solution.

As the sample comes into contact with the membrane of the pH sensor, a potential develops due to the exchange of hydrogen ions in the membrane. The silver/silver chloride wire conducts the potential to a voltmeter where it is compared to the constant potential of the reference sensor. The final measured potential reflects the hydrogen ion concentration of the sample, and is used to calculate the pH value.

Figure 69: pH Sensor (cutaway view)



1. Sensor Contact
2. Inner electrode (Ag/AgCl wire)
3. Fill solution
4. Sample path
5. O-rings

Na^+ Sensor

The Na^+ sensor is based on ISE technology and is a half-cell that forms a complete cell with the external reference sensor. It contains a silver/silver chloride wire (Ag/AgCl) surrounded by an electrolyte solution of fixed sodium and chloride ion concentration. A glass membrane, highly sensitive and specific for sodium ions, separates the sample from the solution.

As the sample comes into contact with the membrane of the Na^+ sensor, a potential develops due to the exchange of sodium ions in the membrane. The silver/silver chloride wire conducts the potential to a voltmeter where it is compared to the constant potential of the reference sensor. The final measured potential is proportional to the sodium ion concentration of the sample.

The Na^+ sensor components are very similar to the pH sensor, shown in *Figure 69*.

K^+ Sensor

The K^+ sensor is based on ISE technology and is a half-cell that forms a complete cell with the external reference sensor. It contains a silver/silver chloride wire (Ag/AgCl) surrounded by an electrolyte solution of fixed potassium ion concentration. The membrane consists of valinomycin (an ionophore) in a plasticized PVC (polyvinylchloride) matrix and separates the sample from the solution. Valinomycin is a neutral ion carrier that is highly sensitive and specific for potassium ions.

As the sample comes into contact with the membrane of the potassium sensor, a potential develops due to the interaction of potassium ions with the membrane. The silver/silver chloride wire conducts the potential to a voltmeter where it is compared to the constant potential of the reference sensor. The final measured potential is proportional to the potassium ion concentration of the sample.

The K^+ sensor components are very similar to the pH sensor, shown in *Figure 69*.

Ca^{++} Sensor

The Ca^{++} sensor is based on ISE technology and is a half-cell that forms a complete cell with the external reference sensor. It contains a silver/silver chloride wire (Ag/AgCl) surrounded by an electrolyte solution of fixed calcium ion concentration. An ionophore in a plasticized PVC (polyvinyl-chloride) matrix forms the membrane and separates the sample from the solution. The ionophore is a compound that is highly sensitive and specific for calcium ions.

As the sample comes into contact with the membrane of the Ca^{++} sensor, a potential develops due to the interaction of calcium ions with the membrane. The silver/silver chloride wire conducts the potential to a voltmeter where it is compared to the constant potential of the reference sensor. The final measured potential is proportional to the calcium ion concentration of the sample.

The Ca^{++} sensor components are very similar to the pH sensor, shown in *Figure 69*.

Cl^- Sensor

The Cl^- sensor is based on ISE technology and is a half-cell that forms a complete cell with the external reference sensor. It contains a silver/silver chloride wire (Ag/AgCl) surrounded by an electrolyte solution of fixed chloride ion concentration. The membrane consists of a derivitized quaternary ammonium compound immobilized in a polymer matrix, and separates the sample from the solution. The membrane acts as an ion exchanger which is highly sensitive and specific for chloride ions.

As the sample comes into contact with the membrane of the chloride sensor, a potential develops due to the exchange of chloride ions at the membrane. The silver/silver chloride wire conducts the potential to a voltmeter where it is compared to the constant potential of the reference sensor. The final measured potential is proportional to the chloride ion concentration of the sample.

The Cl^- sensor components are very similar to the pH sensor, shown in *Figure 69*.

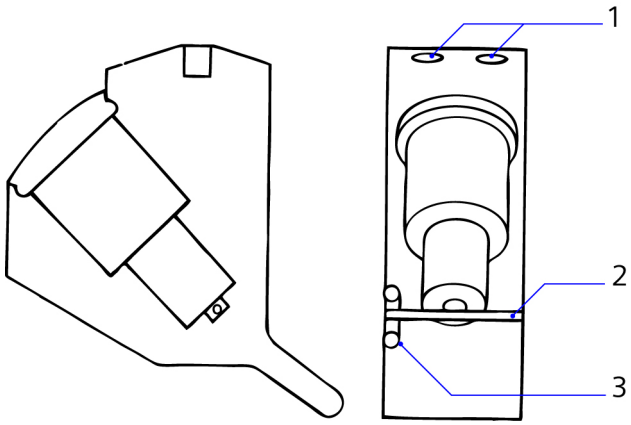
pCO_2 Sensor

The *p*CO_2 sensor is based on the electrode described by Severinghaus and Bradley[18] and consists of a measuring electrode and an internal reference electrode. The measuring electrode, which is a pH electrode, is surrounded by a chloride-bicarbonate solution. A membrane permeable to gaseous CO_2 separates this solution from the sample. The internal reference electrode contains a silver/silver chloride electrode surrounded by the chloride-bicarbonate solution, and provides a fixed potential.

As the sample comes into contact with the membrane, CO_2 diffuses into the chloride-bicarbonate solution causing a change in the hydrogen ion concentration.

The internal pH electrode generates a potential that is compared to the fixed potential of the internal reference electrode. This results in a measurement that reflects pH change in the chloride-bicarbonate solution. The change in pH is proportional to the log of the partial pressure of *p*CO_2.

Figure 70: pCO_2 **Sensor (cutaway view)**



1. Sensor Contacts
2. Sample path
3. O-rings

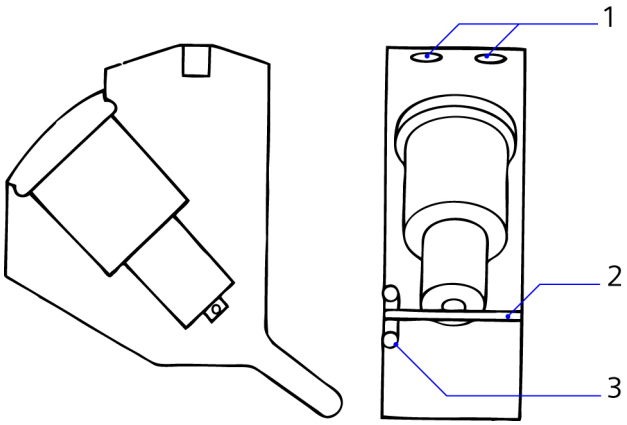
pO_2 Sensor

The pO_2 sensor is based on the electrode described by Clark[19] and uses amperometric technology. The sensor consists of a platinum (Pt) cathode, a silver (Ag) anode, an electrolyte solution and a gas permeable membrane.

A constant voltage, called a polarizing voltage, is maintained between the anode and the cathode. As dissolved oxygen from the sample passes through the membrane into the electrolyte solution, it is reduced at the cathode. The circuit is completed at the anode, where the Ag is oxidized.

The amount of oxygen reduced is directly proportional to the number of electrons gained at the cathode. Therefore, by measuring the change in current (electron flow) between the anode and the cathode, the amount of oxygen in the sample can be determined.[20]

Figure 71: pO_2 **Sensor (cutaway view)**



1. Sensor Contacts
2. Sample path
3. O-rings

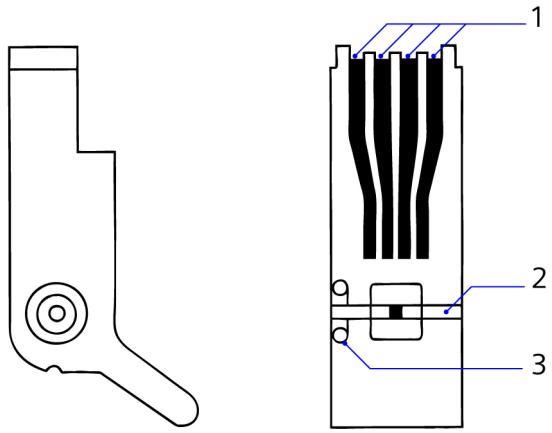
Hct Sensor

The Hct sensor consists of two 4-pole cells connected in parallel. The drive terminal is common to both cells. The Hct sensor also acts as the grounding block for the measurement path.

Conductivity based measurements depend upon the observation that, for relatively low frequency currents, red blood cells act as perfect insulators. The conductivity of these red blood cells is a function of the conductivity of the suspending medium, the volume of suspending cells, and the shape of the cells. A mathematical equation describing the conductivity of a suspension of homogenous spheroids was developed by Fricke.[21] Conductivity based hematocrit measurements are now used in a number of multi-analyte blood gas systems.[22]

As the system also measures the concentration of Na^+ and K^+ ions, which contribute towards the conductivity of the sample, the % Hct can be accurately determined.

Figure 72: Hct sensor (cutaway view)



1. Sensor Contacts
2. Sample path
3. O-rings

Measuring pH, Blood Gases, Electrolytes, and Hct

pH

pH expresses the hydrogen ion activity in a solution as the negative logarithm of the hydrogen ion concentration:

$pH = -\log cH^+$

where cH^+ is the molar concentration of hydrogen ions.

The hydrogen ion is the determinant of the acidity of blood or plasma. Normal cellular metabolism requires an exacting environment where hydrogen ion concentration must be maintained within narrow limits. Hydrogen ion activity reflects the acid-base balance within blood. Acids donate hydrogen ions; bases remove hydrogen ions. The lungs, kidneys and blood all work to maintain the acid-base status within the strict limits necessary.

The Henderson-Hasselbalch equation describes how pH expresses the interaction of acid and base in blood:

pH = pK + log base / acid

where K is the dissociation constant, which describes the ability of a solution to release hydrogen ions. Since K, and therefore pK, is a constant, this equation can be used to demonstrate that pH is proportional to the acid-base concentrations in blood.

pH is clinically significant as a means to determine acid-base disturbances. Acid-base disorders can result in several pathological conditions. An acid-base disorder resulting initially from ventilatory dysfunction is called a primary respiratory acidosis or alkalosis, while one due to renal or gastrointestinal inadequacy is referred to as metabolic acidosis or alkalosis. Using acceptable therapeutic ranges, a pH less than 7.3 indicates acidosis, and a pH greater than 7.5 indicates alkalosis.[23]

pCO_2

Carbon dioxide (CO_2) is produced during normal cell metabolism and is released into the blood stream where it is transported to the kidneys and lungs for excretion. CO_2 is transported through the blood as bicarbonate (HCO_3^-), dissolved CO_2, and carbonic acid (H_2CO_3).

The levels of HCO_3^-, H_2CO_3, and dissolved CO_2 play a major role in maintaining the pH in blood. pH is proportional to the acid-base relationship.

Although other acids and bases are present in the blood, the H_2CO_3/ HCO_3^- relationship is sensitive and dynamic and typically reflects other acid-base changes.

When the measurement of the partial pressure of carbon dioxide (*p*CO_2) in the blood is combined with the measured pH, the values can be incorporated into the Henderson-Hasselbalch equation to determine the HCO_3^- in addition to the *c*tCO_2. Since the *p*CO_2 value is proportional to the content of dissolved CO_2/HCO_3^-, the value for *p*CO_2 can be used with pH not only to calculate HCO_3^-, but also to aid in the differentiation of acid-base abnormalities.

The measurement of *p*CO_2 is essential in determining ventilatory status. Because the lungs are primarily responsible for controlling *p*CO_2 levels, changes in *p*CO_2 reflect respiratory status. For example, an increase in CO_2 indicates decreased ventilation as CO_2 is retained, and a decrease in CO_2 indicates increased ventilation (hyperventilation) as CO_2 is expired from the lungs.

Together, pH and pCO_2 provide a more definitive diagnostic tool in assessing respiratory function. An increase in the pCO_2 value and a decrease in pH indicates respiratory acidosis—a condition where CO_2 is retained by the lungs. A decrease in the pCO_2 value, and an increase in pH indicates respiratory alkalosis—a condition where the lungs are expiring too much CO_2 relative to the amount produced.

pO_2

Oxygen (O_2) is essential for cell and tissue metabolism in the body. The cardiopulmonary system is responsible for transporting oxygen to the cells. Oxygen transport involves four major steps: convection and diffusion from the air into the pulmonary circulation, combination of O_2 from the lungs with haemoglobin in red blood cells, transportation of the O_2 through the arteries to the cell, and finally the release into the tissues and utilization of O_2 at cellular level.

Since it is not possible to measure intra-cellular oxygen tension, arterial pO_2 has become a standard for clinical evaluation of arterial oxygenation status. pO_2(A) measurement, which indicates the oxygen tension in arterial blood, reflects the pressure or driving force for moving oxygen from one location to the next due to pressure differential. Although not a measurement of the O_2 content, this provides a measurement tool to evaluate the pulmonary gas exchange efficiency from an arterial blood sample.

Complete laboratory evaluation of oxygenation requires much more than simple blood gas measurements. Assessment of ventilatory system and acid-base status is essential to properly interpret clinical significance of arterial oxygenation status. However, many patients can be evaluated and treated successfully using blood gases alone if clinical observations and patient history are taken into account.[20]

The measurement of pO_2 is significant in evaluating the degree of hypoxemia (a deficiency of O_2 in arterial blood) present in a patient.

Hct

Hematocrit (Hct) is defined as the volume occupied by red blood cells in a given volume of whole blood and is represented by:

Hct% = (volume occupied by red blood cells/volume of sample) x 100

The major role of hematocrit determinations in critical care is to assess blood loss, and to monitor the recovery after blood loss. Hct values are often used as a criterion for transfusion therapy. Serial hematocrit measurements are recommended when upper GI hemorrhage presents as a clinical emergency, or for rupture of the spleen in children. Following cardiopulmonary bypass surgery, the resultant significant hemodilution causes a fall in hematocrit, and this correlates with hypotension frequently encountered in such surgery.

Hematocrit is of great value in the management of burns patients and in monitoring patients with hemoconcentration associated with trauma and surgery. Hematocrit determinations help evaluate the blood volume status of the infant in the Neonatal Intensive Care Unit. Typically, Hct and Hb in conjunction with blood pressure and maternal history help evaluate whether a transfusion should be given. Hct and Hb are monitored for a sudden decrease which may indicate intracranial hemorrhage.

Na^+

Sodium (Na^+) is the most abundant cation in the extracellular space in the body. It is the major determinant of extracellular osmotic regulation and plays a central role in determining body fluid volume. The kidneys are the primary regulator of sodium and consequently water volume; only minimal amounts of sodium are lost through the skin and other insensible sites. Two regulatory hormones, aldosterone and the antidiuretic hormone (ADH), affect kidney function and hence sodium balance. Aldosterone stimulates the kidneys to reabsorb sodium; ADH stimulates the kidneys to reabsorb water. Maintaining sodium homeostasis is essential in order to regulate body fluids, maintain electrical potential in muscle cells, and control cellular membrane permeability.

Clinically, plasma sodium levels are significant in diagnosing and treating conditions related to sodium imbalance, such as gastroenteritis, vomiting, diarrhea, Addison’s disease, and acute renal failure.

K^+

Potassium (K^+) is the major intracellular cation. It plays an important role in maintaining cell membrane potential in neuromuscular tissue. The normal level within cells is 150 mmol/L, while the normal extracellular potassium level is only 4 mmol/L. A depletion of extracellular potassium causes an increase in the transmembrane electrical potential gradient, which impedes the impulse formation and propagation involved in muscle contraction.

Most potassium is excreted by the kidney, which is the major regulator of potassium output in the body. Actually, the kidney is better at conserving sodium and excreting potassium, so in cases where potassium intake stops, the kidney requires time to adjust and stop excreting potassium. Two hormones, insulin and aldosterone can affect the extracellular level of potassium. Both insulin and aldosterone influence intercellular uptake of potassium, while aldosterone causes increased potassium excretion through the kidney.

Because the serum level of potassium is so small, minor changes can have significant consequences. Therefore, monitoring potassium levels is important especially in patients who are undergoing surgery, or who are experiencing cardiac arrhythmias or acute renal failure, and who are being treated with diuretics. Additionally, regulating serum potassium is significant in cardiac patients who are receiving digitalis therapy, since hypokalemia can increase cardiac sensitivity to digoxin.[24]

Ca^{++}

Ionized calcium (Ca^{++}) is the physiologically active form of calcium, which comprises approximately 45% of the total calcium in plasma. It is essential for the contractility of smooth vascular muscle, and, it plays a vital part in cardiovascular function. It is also important in muscle function, nerve function, bone formation, and it is a cofactor in many cellular hormone and enzyme reactions.

The action of the parathyroid hormone (PTH)—1,25 dihydroxyvitamin D (1,25D)—and calcitonin closely controls the concentration of calcium in extracellular fluid, and regulates the transport of calcium across the gastrointestinal tract, kidney, and bone. Calcium is one of the most tightly controlled analytes in the body with fluctuations of less than 5% occurring about the mean during a 24-hour period.[25]

Clinically, hypocalcemia can result from a deficiency of PTH or 1,25 D, which can be caused by malabsorption of vitamin D, hypoparathyroidism, or chronic renal failure. Hypercalcemia, which occurs more frequently than hypocalcemia, is commonly caused by primary hyperparathyroidism and malignant disease. The elevated calcium resulting from both of these conditions can produce abnormal cardiovascular rhythms.

In critical care situations, especially where large amounts of blood are being transferred, ionized calcium levels should be monitored closely. Transfused blood typically contains citrate as an anticoagulant that can bind ionized calcium and affect its level in the blood. Although total calcium levels may increase, ionized calcium may decrease and lead to cardiac and neuromuscular malfunction.

When measuring ionized calcium, pH should also be measured. Because hydrogen ions compete with calcium for calcium binding sites, a change in sample pH can have a direct effect on calcium levels. For example, a change in pH of 0.1 can cause a change in calcium of 0.2 mg/dL, which exceeds the span of the normal range. Its effects, if not taken into account, are clearly significant.[26]

Cl^-

Chloride (Cl^-) is the major extracellular anion in the body. It plays a large role in maintaining electrical neutrality and normal osmolality, and it participates in the regulation of acid-base balance. The kidneys are the main regulator of chloride in the body. Serum levels of chloride usually correspond to increases and decreases of sodium. Clinically, the serum chloride level alone is rather meaningless. A change in chloride level does not reveal much about a patient's condition; it must be viewed as part of the overall fluid and electrolyte status.

Hypochloremia is usually seen in states of hyponatremia. However in pyloric stenosis, chloride levels are usually proportionally lower than sodium levels. Hyperchloremia is seen in cases of excessive administration of chloride and in renal failure. Additionally, because the chloride level remains fairly constant, it is valuable in the calculation of the anion gap.

Calculated Parameters

The system calculates other parameters of interest to clinicians and uses several different equations to provide these parameters. Unless otherwise noted, all measured values used in equations are at 37°C.

Bicarbonate Ion (HCO_3^-)

Bicarbonate (HCO_3^-) is the major buffer substance present in the body, and plays a major role in maintaining the pH level in blood. It is present in large amounts in the blood as a result of the dynamic state of CO_2 in the blood. The majority of CO_2 is transported as HCO_3^-.

The kidneys are the major controller of bicarbonate ion. Bicarbonate levels are clinically significant in helping to determine the non-respiratory, renal (metabolic) component in acid-base disorders.

Changes in HCO_3^- levels, along with pH values, can help determine if acidosis or alkalosis disorders are of metabolic origin. In metabolic acidosis, HCO_3^- levels decrease, causing an increase in H^+, which leads to a decrease in pH. Conversely, in metabolic alkalosis, HCO_3^- levels increase, causing a decrease in H^+ which leads to an increase in pH.

There are 2 versions of bicarbonate, the actual value and the standard value, available in the System Set Up menu.

Actual Bicarbonate ($HCO_3^-{}_{act}$)

Based on the Clinical Laboratory Standards Institute (CLSI) recommendations[27]:

$$cHCO_3^-{}_{act} = 0.0307 \times pCO_2 \times 10^{(pH - 6.105)}$$

Standard Bicarbonate ($HCO_3^-{}_{std}$)

The equation described by VanSlyke and Cullin[28] is used for calculating standard bicarbonate:

$$cHCO_3^-{}_{std} = 24.5 + 0.9A + (A - 2.9)^2 (2.65 + 0.31 ctHb)/1000$$

where $A = BE(B) - (0.2 ctHb(100 - O_2SAT)/100)$

Base Excess

Base excess is an empirical expression that approximates the amount of acid or base required to titrate one litre of blood back to a normal pH of 7.4. The base excess in blood with a pH of 7.4, pCO_2 of 40 mmHg (5.33 kPa), total haemoglobin of 15 g/dL and a temperature of 37°C is zero. Base excess is useful in the management of patients with acid-base disorders, as it allows the estimation of the number of equivalents of sodium bicarbonate or ammonium chloride required to correct the patient's pH to normal.

There are 2 versions of base excess, available in the System Set Up menu.

Base Excess of Extracellular Fluid (BE(ecf))

The base excess of extracellular fluid, formerly known as *in vivo* base excess, reflects only the non-respiratory component of pH disturbances:

$$BE(ecf) = cHCO_3^-{}_{act} - 24.8 + 16.2 (pH - 7.4)$$

Base Excess of Blood (BE(B))

The base excess of blood, formerly known as *in vitro* base excess, is calculated from the following equation:

$BE(B) = (1 - 0.014ctHb)\ (cHCO3^{-}_{act} - 24.8 + (1.43ctHb + 7.7)\ (pH - 7.4))$

If no *c*tHb value has been entered, a value of 15 g/dL is assumed.

Oxygen Content (O_2CT)

Oxygen content is the concentration of the total oxygen carried by the blood, including oxygen bound to haemoglobin as well as oxygen dissolved in plasma and in the fluid within red cells.

Oxygen content is calculated, using CLSI recommendations[29], as follows:

$O_2CT = (1.39ctHb \times O_2SAT/100) + (0.00314pO_2)$

where *c*tHb is expressed in g/dL.

If no *c*tHb value has been entered, or if *c*tHb(est) is not available, O_2CT is not calculated.

Clinically, dissolved oxygen is for most situations analytically unimportant. However, at very low levels of haemoglobin or in patients receiving hyperbaric oxygen therapy, dissolved oxygen may be a very significant contributor to oxygen transport.

Oxygen Saturation (Estimated)

Oxygen saturation (O_2SAT) is a ratio, expressed as a percentage of the volume of oxygen carried to the maximum volume that can be carried. Knowledge of oxygen saturation is useful for predicting the amount of oxygen actually available for the tissues and can be used to determine the effectiveness of oxygen therapy.

Note Clinically significant errors can result from incorporating an estimated O_2SAT value in further calculations, such as shunt fraction (Qsp/Qt), or by assuming that the value obtained is equivalent to fractional oxyhaemoglobin.[29]

$O_2SAT = N^4 - 15N^3 + 2045N^2 + 2000N/N^4 - 15N^3 + 2400N^2 - 31{,}100N + (2.4 \times 10^6) \times 100$

where $N = pO_2 \times 10^{[0.48(pH-7.4) - 0.0013\ BE(B)]}$

Because oxygen saturation also depends on the level of carbon monoxide and 2, 3 diphosphoglycerate (2, 3 DPG) in the blood, the calculated value for oxygen saturation may not be equal to that actually measured for patients showing abnormal levels of 2, 3 DPG or carbon monoxide. The equation does not account for these variations, therefore the oxygen saturation that is reported should be used only as an estimate of the actual value.

Total Carbon Dioxide (ctCO$_2$)

Total carbon dioxide (ctCO$_2$), in combination with pH and pCO$_2$, is useful in distinguishing between metabolic and respiratory acid-base disorders.

Carbon dioxide exists in several forms in blood plasma, but only 2 forms, dissolved CO_2 and HCO_3^- are quantitatively significant. Based on CLSI recommendations[27], the following equation is used:

$$c\text{tCO}_2 = c\text{HCO}_3^-{}_{\text{act}} + (0.0307 \times p\text{CO}_2)$$

Patient Temperature Correction

All measurements and calculations are based on a standard temperature of 37°C. Actual patient temperature values can be entered during sample analysis, which allows the RAPIDLab 348EX system to provide temperature-corrected results. The following equations, based on CLSI recommendations[27], are used:

$$\text{pH(T)} = \text{pH} - (0.0147 - 0.0065 \times (7.4 - \text{pH})) \times (\text{T} - 37)$$

$$p\text{CO}_2(\text{T}) = p\text{CO}_2 \times 10^{(0.019 \times (\text{T} - 37))}$$

$$p\text{O}_2(\text{T}) = p\text{O}_2 \times 10^{(\text{A} \times (\text{T} - 37))}$$

where $\text{A} = 5.49 \times 10^{-11} \times p\text{O}_2{}^{3.88} + 0.071 / 9.72 \times 10^{-9} \times p\text{O}_2{}^{3.88} + 2.3$

and where T = 37°C if not entered.

ctHb(est)

ctHb is used in calculated parameters. The system uses ctHb values in the following precedence: entered (obtained from a direct measuring method), estimated from the system Hct value, or the default setting of 15 g/dL.

Note The system does not calculate O_2CT if entered ctHb or ctHb(est) is not available.

The system estimates ctHb using the following equation:

$$c\text{tHb(est)} = \text{Hct (\%)} / 2.941$$

Gas Exchange Indices

Gas exchange indices are a quick way to estimate the relationship between pulmonary dysfunction and hypoxia and to quantitatively determine the degree of pulmonary shunting. However, they do not have a high level of correlation with the actual measurement of arterial and mixed venous blood and should be used with discretion. The gas exchange indices are provided for convenience. Final judgment of their use is in the hands of the physician. The gas exchange indices require an arterial sample and use measured values at patient temperature.

Alveolar O_2

Alveolar O_2, referred to as $pO_2(A)$ or pAO_2, is the partial pressure of oxygen in alveolar gas. It is a primary component in the detection of gas exchange indices. The following equation[20, 30] is used to estimate the alveolar O_2:

$$pO_2(A)(T) = F_IO_2/100 \times (p\text{Atm} - pH_2O) - pCO_2(T) \times (1.25 - 0.25 \times F_IO_2 / 100)$$

$$pH_2O = 10^{(0.0244 \times T + 0.7655)} + 0.4$$

Arterial-Alveolar Oxygen Tension Difference

The arterial-alveolar oxygen tension difference ($pO_2(A–a)$), (or $A–aDO_2$) is useful as an index of gas exchange within the lungs if ctO_2 measurements are not available. The following equation[20, 30] is used:

$$pO_2(A–a)(T) = pO_2(A)(T) – pO_2(a)(T)$$

where $pO_2(A)(T)$ is the temperature corrected oxygen tension of alveolar gas, and $pO_2(a)(T)$ is the temperature corrected oxygen tension of arterial blood.

Arterial-Alveolar Oxygen Tension Ratio

The arterial-alveolar oxygen tension ratio ($pO_2(a/A)$), (or a/A ratio) provides an index of oxygenation that remains relatively stable when F_IO_2 changes. It is useful in predicting oxygen tension in alveolar gas.

$$pO_2(a/A)(T) = pO_2(a)(T) / pO_2(A)(T)$$

where $pO_2(A)(T)$ is the temperature-corrected oxygen tension of alveolar gas, and $pO_2(a)(T)$ is the temperature corrected oxygen tension of arterial blood.

Note If F_IO_2 value is not entered, the gas exchange indices are not calculated.

Calcium Adjustment for pH

Ionized calcium values are dependent on sample pH. The calcium value adjusted to pH 7.40 reflects the true ionized calcium concentration of blood normalized to pH 7.40. The calcium value is adjusted according to the following equation[32];

adjusted Ca^{++} = Ca^{++} measured x $10^{-0.178[7.40\ pH - measured\ pH]}$

The calcium value is adjusted only when the measured pH is between 7.2 and 7.7 at 37°C, as no reliable, published clinical data is available outside that range.

Anion Gap

The anion gap (AnGap) is an approximation of the difference between unmeasured cations and unmeasured anions. Historically, several formulas have been used to mathematically approximate the balance of these unmeasured ions.

An anion gap result is of twofold value in a clinical laboratory. Primarily, abnormal anion gap results indicate electrolyte imbalance or other conditions where electroneutrality is disrupted, such as seen with diabetes, toxin ingestion, lactic acidosis, or dehydration. Secondly, the anion gap result is useful for quality assurance of laboratory results. If an increased or decreased anion gap result is calculated from a non-diseased individual this indicates the possibility of one or more erroneous electrolyte results.

The system calculates anion gap using the following equation:

$AnGap = (Na^+ + K^+) - (Cl^- + HCO_3^-act)$

pO_2/F_IO_2 Ratio

The arterial oxygen tension (pO_2) to inspired oxygen concentration (F_IO_2) ratio was introduced in the 1970s to avoid calculation of alveolar pO_2.[33, 34] The ratio has achieved some utility as an oxygenation index if shunt parameters are not available. The accuracy with which the ratio reflects shunt varies in the literature.[35] In a heterogenous group of critically ill patients Cane *et al* found the ratio, in terms of affecting shunt, to be somewhat comparable to the Respiratory Index and the arterial to alveolar ratio.[35] However, a number of intensive care physicians favor the use of the pO_2/F_IO_2 ratio as an oxygenation index.

The system calculates the pO_2/F_IO_2 ratio using the following equation:

$pO_2 / F_IO_2 = pO_2$ (mmHg) / F_IO_2(%)

Note If F_IO_2 value is not entered, the gas exchange indices are not calculated.

The algorithms used for Calculated Parameters are those currently recommended by CLSI. Algorithms used in our earlier instruments are given here for reference:

Actual Bicarbonate ($HCO_3^-_{act}$)

$HCO_3^-_{act} = 0.031 \times pCO_2 \times 10^{(pH - 6.1)}$

Standard Bicarbonate ($HCO_3^-_{std}$)

Same as for earlier instruments.

Base Excess of Extracellular Fluid (BE(ecf))

In earlier instruments, this was (vv)

$BE(ecf) = (1 - 0.004ctHb) \times (HCO_3^-_{act} - 24) + (9 + 0.3ctHb) \times (pH - 7.4) - 0.3ctHb \times (100 - O_2SAT)/100$

Base Excess of Blood (BE(B))

In earlier instruments, this was BE(vt)

$BE(B) = (1 - 0.014ctHb) \times (HCO_3^-_{act} - 24) + (9.5 + 1.63ctHb) \times (pH - 7.4)$

Oxygen Content (O_2CT)

$O_2CT = 1.39ctHb \times O_2SAT/100 + 0.003\ pO_2$

Oxygen Saturation (Estimated)

Same as for earlier instruments.

Total Carbon Dioxide ($ctCO_2$)

$ctCO_2 = 0.031pCO_2 + HCO_3^-_{act}$

Patient Temperature Correction

$pH(T) = pH - 0.015 \times (T - 37)$

pCO_2 same as for earlier instruments.

$pO_2(T) = pO_2 \times 10^{(A \times (T - 37))}$

where $A = 0.0052 + 0.027 \times (1 - 10^{(-0.13 \times (100 - O2SAT))})$

Arterial-Alveolar Oxygen Tension Difference

Same as for earlier instruments.

Arterial-Alveolar Oxygen Tension Ratio

Same as for earlier instruments.

Revision History

10698292 Rev. E

Chapter/Appendix	Description of Change
Table of contents	Added headings “Summary and Explanation”, “Shelf Life”, “Materials Provided”, “Special Materials Required (Not Provided)”, “Reference Ranges”, “IT Security”, “Disposal of the Analyzer”, “Technical Assistance”, “Training”, “Limit of Quantitation”, “RAPIDLab 348EX Parameter Linearity”, “RAPIDLab 348EX Interfering Substances”, “Irenat Interference”, "Method Comparison – RL348EX Blood Gas", and "Method Comparison – RL348EX Dialysis Fluid".
Introduction	Added section “Summary and Explanation”. Updated section “Intended Use of the RAPIDLab 348EX System” with testing population.
Handling Samples and Reagents	Added section “Shelf Life”.
System Operation	Added section "Materials Provided" and "Special Materials Required (Not Provided)”.
System Installation and Configuration	Added electromagnetic caution statement in section “Installation”.
Appendix A: Concepts and Reference Information	Updated section “Setting Reference Ranges” with information about values used for reference ranges. Added section “Reference Ranges”.
Appendix B: Warranty and Support Information	Added section “IT Security”, “Disposal of the Analyzer”, and "Training". Updated section heading "Technical Assistance" and added “EUDAMED” statement and information about adverse incident to the user in that section.

Chapter/Appendix	Description of Change
Appendix E: References	Updated section “References” with additional literature references.
Appendix F: Specifications	Added storage information in section “Specifications”. Added section “Limit of Quantitation”, “RAPIDLab 348EX Parameter Linearity”, “RAPIDLab 348EX Interfering Substances", "Irenat Interference", "Method Comparison – RL348EX Blood Gas", and "Method Comparison – RL348EX Dialysis Fluid".
Appendix G: Symbols	Updated “Serial Number” symbol. Added “Device for near patient testing” symbol with the description.
*	Updated web address to “siemens-healthineers.com/poc” in EC-REP.

* Indicates the changes are common and not included in any particular sections of this Operator’s Guide.

10698292 Rev. F

Chapter/Appendix	Description of Change
Table of contents	Added headings “Global Harmonized System of Classification and Labeling of Chemicals”, “Introduction”, “GHS Information”, “Hazard and Precaution Information”, "Composition of the reagents and the concentration of the active ingredients", "Final concentration of preservatives and toxic substances in the individual components/products", "Sensitivity of ISE Sensors", "Limitations", and “Revision History”.
Safety Information	Updated TÜV SÜD symbol and description. Updated section “Operating Precautions”. Added section “Global Harmonized System of Classification and Labeling of Chemicals”.
Introduction	Updated information about results in the section “Intended Use of the RAPIDLab 348EX System”. Updated “Summary and Explanation” section.
Handling Samples and Reagents	Updated "Sample Collection Devices", "Storage", and "Shelf Life” sections. Removed “Active Ingredients” section. Added sections "Composition of the reagents and the concentration of the active ingredients" and "Final concentration of preservatives and toxic substances in the individual components/ products".
System Operation	Updated section “Materials Provided”. Removed section “Special Materials Required (Not Provided)”.
System Installation and Configuration	Updated section "Installation Procedure".
Appendix C: Orderable Supplies	Updated section "Orderable Spares" and "Reagents".

Chapter/Appendix	Description of Change
Appendix F: Specifications	Updated sections "Measured Parameters", "Limit of quantitation", "RAPIDLab 348EX Parameter Linearity", "RAPIDLab 348EX Interfering Substances", and "Measured Parameters - Dialysis Fluid Mode". Added section "Sensitivity of ISE Sensors".
Appendix G: Symbols	Updated TÜV SÜD symbol and description. Updated CE mark and description.
*	Added list of products with their SMNs on page 2. Removed Registered trademark symbols. Updated trademark statement on page 4. Updated Siemens Heathineers Headquarters address.

* Indicates the changes are common and not included in any particular sections of this Operator's Guide.

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