SIEMENS Healthineers

RAPIDPoint® 500e
Blood Gas System

Siemens Healthcare Diagnostics Inc.

Customer Bulletin

2021-07

RAPIDPoint 500e Blood Gas System V5.1/V5.1.1 Release Notes

Introduction

Note The V5.1 and V5.1.1 software releases are identical in respect to all features and instructions. The only respect in which they differ is that the V5.1.1 software is installed using the teamplay Fleet application.

The following features have been integrated into the RAPIDPoint® 500e system with the release of software V5.1/5.1.1:

- Users can enter reference and critical range limits for all patient sample options.
- Users can reject patient sample results, and record notes for critical values and rejected results.
- Reference value tables for a range of sample types are provided in this bulletin as a convenience to support manual reference range entry. Default reference range values for arterial samples are automatically populated in RAPIDPoint 500e systems for users receiving new systems.
- The External Quality Assurance (EQA) sample type, which enables a one-step process to perform EQA (proficiency) tests, is now available.
- Users can install software remotely as soon as it is available, which enhances system security and functionality, and streamlines the install process through use of the teamplay Fleet application.[1]
- The patient demographics sources enhancement provide greater flexibility for populating patient demographics.
- Microsoft OS updates have been implemented.

New Features

Enhancements

1. Availability of teamplay Fleet varies by country. Contact your local Siemens representative for more information.

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11555658 Rev.C

Critical Ranges

Critical range results indicate a patient needs urgent medical attention. When critical range limits are entered in a RAPIDPoint 500e system, the operator is alerted to any results that are out of critical range limits by visual indicators on-screen, in printed reports, and in results sent to the LIS.

Critical Ranges features

- User-defined low and high critical range limits can be entered manually in the RAPIDPoint 500e system for all measured parameters, for a subset of calculated parameters, and for arterial, venous, mixed venous, capillary, dialysate,[2] and pleural fluid pH sample types.
- When critical range limits are entered, critical range results are indicated on-screen in white text against a red background, which alerts operators to the importance of these results.
- Critical range flags, on-screen in the **Results** and **Recall** screens, and in printed reports, indicate when a parameter is outside the critical range limit. High critical range results are indicated by "↑ ↑." Low critical range results are indicated by "↓ ↓." Result values display next to the flag.
- Results above or below the RAPIDPoint 500e instrument range[3] or the analytical measurement range (AMR,[4] also known as the "analytical range") qualify as critical results because these results would be below or above critical range limits.

  On-screen, these results display in white text against a red background, indicting that the values qualify as critical results, and they retain the flags assigned to indicate each type of range ("-----↓", "----↑" for out-of-instrument range values, and "< ", ">" for out-of- AMR range values).
- If critical ranges are not entered for a parameter, other values that are out of a measurement range display in red with the applicable flag.
- The **More Results** button displays in red if any critical range results are flagged at the **More Results** screen.
- In printed reports, critical results are indicated by critical range flags. Out-of-AMR and out-of-instrument range values are indicated by the existing flags for those states.

  Note New options have been introduced for printing reports which operators may find useful (see *page 9*).
- When sent to the LIS, low critical range values are indicated by "LL" and high critical range values by "HH."

2. The dialysate sample type is not available in the US and Canada.
3. The "instrument range" is the full range of parameter values the RAPIDPoint 500e is capable of measuring.
4. "AMR" is the range of values an instrument can measure with verifiable accuracy as defined by the institution.

Entering Critical Range Limits

Figure 1-1: Patient Ranges Screen

1 **Setup**

2 **Patient Ranges**

3 Currently selected parameter

4 **Edit**

Procedure

Note Reference range values can also be entered using this procedure.

Note Critical range limits must be entered manually, based on values determined by your site.[5]

1. At the **System** screen, select **Setup** > **Sample** > **Patient Ranges**.
2. At the **Patient Ranges** screen, highlight the parameter for which you want to enter critical range limit values (use the arrow key to scroll to the parameter, if needed).

   Note To print a report that shows all currently configured measurement ranges for all current sample types, select the **Print** icon.

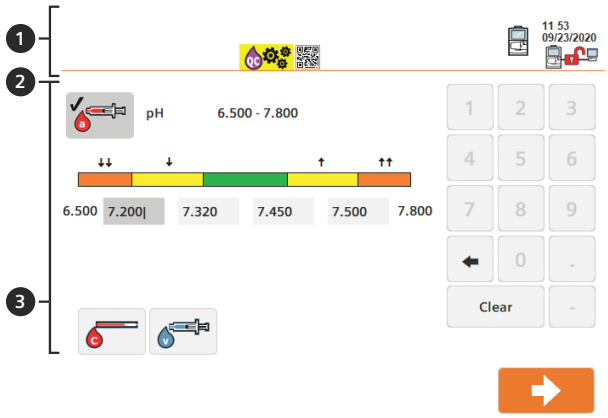
   Note With this release, users can enter both critical range limits and reference range values for the dialysate[6] sample type. In addition, the dialysate and pleural fluid pH sample types may now both be enabled as selectable options at the **Analysis** screen. Previously, only one of these sample types displayed at a time.

3. Select **Edit**.

5. To configure multiple RAPIDPoint 500e systems to use the same measurement range settings after entering measurement values in one system, see *Saving and Restoring System Setup Data* in chapter 8 of the *RAPIDPoint 500e Blood Gas System Operator's Guide*.
6. The dialysate sample type is not available in the US and Canada.

The **Patient Ranges Edit** screen displays. Values for the lower and the upper range limits for critical ranges are entered at this screen.

Figure 1-2: Patient Ranges Edit Screen



1 **Setup**

2 **Patient Ranges Edit**

3 **Apply Ranges to...**

4. Use the numeric keypad to enter low and high critical range limit values in the low critical range limit field (7.200 in the example above) and the high critical range limit field (7.500 in the example above). The low and high critical ranges display as orange in the measurement bar.

   Note Only one value needs to be entered for the low critical range limit and only one value for the high critical range limit, as shown above. The boundary limits below and above the critical ranges are defined by the instrument range limits.

   The reference range displays as green in the measurement bar. Reference range values are also entered at this screen. In the example above, reference range values of 7.320 and 7.450 are entered.

   Note The yellow ranges indicate values below or above the reference range, which are cause for medical concern but are not critical.

5. If desired, you can apply the range limit values you have entered to other sample types, if they are applicable to the current parameter, by selecting one or more of the sample type icon buttons that display under **Apply Ranges to...**. Multiple sample types can be selected at the same time.

   Note Be careful to only select sample types for which the entered critical value limits are appropriate.

6. Select the **Continue** button.

Using the Critical Value Notification Feature

Enabling Critical Value Notification

Note A security level of 1 is required to use this feature.

Note To extend the time available to view and enter information, see *Extending the Time Available to View Results, page 8*.

Procedure

1. At the **System** screen, select **Setup** > **Secured Options** > **Analysis Options.**
2. Select **Critical Value Notification**.

When **Critical Value Notification** is enabled and results below or above a critical range limit are reported, the **Critical Value Notification** icon, which shows an image of a healthcare professional, displays in red at the top-right of the **Results** screen. The red icon indicates critical value notification is required, while white or gray icons indicate notification is optional or, when a check mark displays, that notification has been completed.

Selecting this icon displays the **Critical Value Notification** screen.

- The **Critical Value Notification** screen allows selection of between 1 and 6 critical value action options, entry of time and date, whether the result was read back, and allows entry of a brief comment.

Selecting Critical Value Notification Options

The **Critical Value Notification** icon displays in the top-right of the screen at the **Results** screen when **Critical Value Notification** is enabled. The icon will be red when a value outside critical range limits is detected. The icon will be gray when there are not values outside of critical range limits (and therefore the notification is optional). After the operator enters a notification, the icon turns white and displays with a check mark.

Notification Required

Notification Optional

Notification Completed

Procedure

1. At the **Results** screen, select the **Critical Value Notification** icon.

   The **Critical Value Notification** screen displays.

   Under **Action Taken**, 6 notification options are indicated:

   - **Notified Physician**
   - **Notified Nurse**
   - **Repeated Test**
   - **Sent to Lab**
   - **Expected Result**
   - **Other**

2. Before selecting one or more notifications, perform the action(s) taken to address the critical results.
3. Select the action(s) you have performed from the **Action Taken** list on-screen. If you select **Other**, you must enter a text comment (see 4).

   You can select between 1 and 6 notifications.

4. You can enter text In the **Comment** field to provide details about an action that has been taken. For example, if **Notified Physician** was selected, “Dr. Amala” might be entered in the comment field. Up to 30 characters can be entered in the **Comment** field.
5. The current date and time are automatically entered in the corresponding field but can be edited using the on-screen keypad. Error messages display if the data entered is in an invalid format or if a field requiring data is empty.
6. If confirmation has been received that critical results have been received by the physician, nurse, or both, select the **Read back?** toggle button to set the notification to a **Yes** value. When unselected, this button is set to **No**, which is its default state.
7. After selecting notifications in the **Critical Value Notification** screen and selecting **Continue**, you are returned to the **Results** screen. The **Critical Value Notification** icon that is visible at the **Results** (or **More Results**) screen turns white and displays with a check mark, indicating the critical value notification has been successfully recorded.

8. If you have not selected a notification or entered a comment when required, the following message will display when you select **Continue** at the **Results** screen, after accessing and leaving the **Critical Value Notification** screen:

   Critical Value Notification or Reject Results reason information data entry has not been completed.

   Touch **Yes** to save the incomplete data entry, which cannot be edited in **Recall**.

   Touch **No** to return to the screen to complete data entry.

   a. Select **Yes** to continue without completing data entry or **No** to return to the notifications screen to complete data entry before selecting **Continue.**

Note Information entered for **Critical Value Notification** can be viewed but not edited at the **Recall Patient** list screen. Critical values that are present on screen are indicated by critical range flags (" ⇊ " , " ⇈ ").

Critical Value Notifications in Printed Reports

When notifications are entered for a critical value result, the notification information entered on-screen is printed in the report. The time and date will always be printed, along with the following information, if selected or entered:

- **Action Taken**: Between 1 and 6 of the selectable actions taken.
- **Comment:** Up to 30 characters.
- **Read Back?**: If toggled on, **Yes** is identified as the **Read Back?** value, indicating the selected **Action Taken** has been confirmed. If toggled off, which is the default state, **No** is indicated (if more than one action has been taken, **Read Back?** applies to all actions taken).

Note Results will not auto-print, or auto-send to the LIS, until the critical value notification or reject results activities have been completed and the result has been finalized by selecting the **Continue** button to leave the **Results** screen.

If an operator previews the results in the print report by selecting the print icon at the **Results** screen, and results have not yet been finalized by selecting the **Continue** button, the message **PRELIMINARY RESULTS** will be included in the report.

Critical Value Notifications Sent to the LIS

Note We recommend that you confer with your local IT support team to determine if your LIS system has the capability to interpret notification information. Some LIS systems will need to be configured and some LIS systems may be incompatible with notification messaging.

When notifications are sent to the LIS, and the LIS is configured to interpret the notification, the following information is entered in the LIS:

- **Action Taken**: Between 1 and 6 of the selectable actions taken.
- **Comment:** Up to 30 characters.
- **Read Back**?: If toggled on, **Yes** is identified as the **Read Back?** value, indicating the selected **Action Taken** has been confirmed. If toggled off, which is the default state, **No** is indicated.

For more information on results sent to POCcelerator™ or another LIS, see chapter 3 of the *RAPIDPoint 500e Blood Gas System Interface Specifications Manual*.

Extending the Time Available to View Results

To ensure the **Results** screen does not revert to the **Analysis** screen automatically before data is entered for **Critical Value Notification**, **Non-Critical Value Notification**, or **Reject Reason**, you can set a timer that extends the time to view the **Results** screen.

Note A security level of 1 is required to use this feature.

Note The default value of the timer is 2 minutes.

1. At the **System** screen, select **Setup** > **Secured Options**> **Analysis Options.**
2. Under **Result Screen Timeout**, select one of the following, which represent time in minutes (the ∞ symbol indicates unlimited time to view results):
   - **2**
   - **5**
   - **10**
   - **15**
   - ∞
3. Select the **Continue** button.

   Extending the time available at the **Results** screen enables users to take time to view results and perform the actions needed to respond to critical value results, for example to notify a nurse, before indicating the actions taken at the **Critical Value Notification** screen.
   The **Critical Value Notification** screen does not have a time limit.

Note When a timeout expires, the information that is currently entered for notifications is processed by the RAPIDPoint 500e system. This information cannot be changed at the **Recall** screen.

Note The timeout option applies only to the **Results** and **More Results** screens, and does not apply to the **Critical Value Notification** and **Reject Reason** screens, which are not subject to timing out. Timeouts only apply during analysis and do not apply to recall activities.

Critical Ranges and Results in Printed Reports

Three Printed Report Options

With the introduction of site-definable **Critical Ranges**, three types of reports are available to print results and measurement ranges:

- **None**: Only result values for individual parameters are printed. The critical ranges and the reference range are not indicated.
- **Flagged Values**: All parameter values are shown, but ranges are only shown for those parameters that have flagged results.
- **All**: All parameter results display, along with the relevant measurement ranges, which may include the reference range and critical ranges, if enabled.

Procedure

1. At the **System** screen, select **Setup** > **Printer and Devices**> **Printer Options**.
2. At the **Printer Options** screen, under **Patient Ranges** select one of the following 3 report formats:
   - **None**
   - **Flagged**
   - **All**
3. Select **Patient Sample Report** under **Auto Print**, if you want to have the report printed automatically.

   Note Auto-print is deferred until critical value notification, reject results, or both are completed, if enabled. Manual printouts will indicate **Preliminary Results** if printed prior to completing critical value notification or reject results.
4. Select **Continue** 3 times.

How Measurement Ranges are Indicated in Printed Reports

In printed reports, the "↓ ↓" flag indicates any result below the low critical range limit, and the "↑ ↑" flag indicates any result above the critical range limit. Numerical results are shown.

Results below the low reference range are indicated by "↓" and results above the high reference range by "↑." Numerical results are shown.

Results below the instrument range are indicated by "----↓" and results above the instrument range by "----↑", without a numerical value. Results below the AMR range are indicated by "<", and results above the AMR by ">", with the AMR limit values next to the flags.

Critical Range Results Sent to the LIS

When sent to a POCcelerator or another LIS system, results below the low critical range limit are indicated by "LL" and results above the high critical range limit are indicated by "HH."

If critical ranges have been selected, results that are below or above the AMR range, or below or above the instrument range are also indicated as critical range results with "LL" and "HH" flags (for more information, see chapter 3 of the *RAPIDPoint 500e Blood Gas System Interface Specifications Manual*).

Rejecting Results

An operator may choose to reject a result, either because the result is questionable, for example when a mixing error occurs, or when a result is not appropriate for that database and should therefore be indicated as a rejected result, as in the case of EQA results.

With this release, operators can reject patient sample results. When a result is rejected, the result is indicated as rejected on-screen, in printed reports, and in results data sent to the LIS.

In addition, the operator can record a reason for rejecting the result and provide a comment to support the explanation, using the **Reject Reason** feature.

Results can be rejected at the **Results** screen after analysis completes. The reason for rejecting the result, and comment if entered, can be viewed but not edited at the **Recall** screen, and displays in printed reports, and in the LIS.

To enable the **Reject Results** feature, to reject a result and, optionally, to record a reason for rejecting the result, follow the procedures below.

Procedures

Enabling the Reject Results feature

Note A security level of 1 is required to use this feature.

Note The **Reject Results** feature is off by default.

1. At the **Setup screen**, select **Secured Options** > **Analysis Options.**
2. At the **Analysis Options** screen, select **Allow Reject Result**.

   The **Reject Results** button will now display at the **Results** screens following sample analysis.
3. Select the **Continue** button 2 times.

Rejecting Results and Entering a Reject Reason Notification

After you enable **Reject Results**, use the following procedure to reject results and, optionally, to enter a notification that records the reason you have rejected the results.

Note To extend the time available for an operator to enter information, see *Extending the Time Available to View Results*, page 8.

1. To reject results after running a patient sample, select **Reject Results** at the **Results** screen.

   The **Reject Reason** screen displays

   When results have been rejected, a thought bubble icon button displays to the right of the **Reject Results** button, which enables viewing and editing of the **Reject Reason** options.

   Note The **Reject Results** button is a toggle button. If you select the button again after you first selected it to reject results, your selection of **Reject Results** is undone, the thought bubble button no longer displays, and the results are accepted when you select the **Continue** button or when the timer expires.
2. Select one of the following reasons for rejecting the sample:
   - **Sample incorrectly identified**
   - **Sample integrity issues**
   - **Clots**
   - **Bubbles**
   - **Operator Competency test sample**
   - **EQA sample**
   - **Other**
3. If you select **Other**, or you want to add additional information about the rejected sample, enter a comment in the text field that is available below **Comment**, which allows entry of up to 30 characters.

4. Select the **Continue** button.

   Note If you select **Other** but do not enter text, when you select **Continue** a message reminds you to complete the entry (see page 7).

   Note **Reject Reason** displays with a check mark and the thought bubble displays.

5. Select the **Continue** button.

Rejected Results and Reject Reason in Printed Reports

If **Reject Results** is enabled, the following reject status indicators are printed in the report for that sample:

- If an operator has rejected a result, the message **Rejected Results** is sent to the printer.
- If the operator does not reject the result, the message **Accepted Results** is sent to the printer.
- If an operator previews the results in the print report by selecting the print icon at the **Results** screen, and results have not yet been finalized by selecting the **Continue** button, the message **PRELIMINARY RESULTS** will be included in the report.

  Note The **PRELIMINAY RESULTS** message only displays on printouts prior to a result being finalized by selection of the **Continue** button.

When a **Reject Reason** notification is entered, the notification information entered on-screen is printed in the report:

- **Reject Reason**: 1 or more of the 7 reasons selected for rejecting the sample.
- **Comment:** Up to 30 characters.

Rejected Results and Reject Reason Sent to the LIS

Note We recommend that you confer with your local IT support team to determine if your LIS system has the capability to interpret notification information. Some LIS systems will need to be configured and other LIS systems may be incompatible with notification messaging. For more information, see chapter 3 of the *RAPIDPoint 500e Blood Gas System Interface Specifications Manual*.

If **Reject Results** is enabled, the following reject status indicators are sent to the LIS for that sample:

- If an operator has rejected a result, the message **REJECTED** is sent to the LIS.
- If the operator does not reject the result, the message **ACCEPTED** is sent to the LIS.

When notifications are sent to the LIS the following information is sent to the LIS:

- **Reject Reason**: The reason selected for rejecting the sample.
- **Comment:** Up to 30 characters.

Rejected Results and Reject Reason at the Recall Screen

- Rejected results are indicated by an **X** at the **Recall Patient** list screen.
- The **Reject Reason** and **Comment** display at the **Recall** screen, but cannot be edited.

Default Reference Ranges for Arterial Samples

Note The default reference range feature is implemented only for customers who receive new RAPIDPoint 500e systems with the release of the V5.1/5.1.1 software. For existing customers who upgrade from versions prior to V5.1, the patient ranges previously entered will be used for reference ranges.

Note Reference ranges are also known as "normal values," "reference intervals," and "established ranges."

Reference range values define which parameter results are normal and indicate a healthy state. Values below or above the reference range, but not in the critical range, indicate results that may be cause for medical concern but which are not critical.

With this release, reference range values for arterial samples are pre-populated in the software for new RAPIDPoint 500e systems. These values can be used for evaluative purposes until a facility implements its own site-specific reference range values.[7] Default reference range arterial sample values are implemented for all measured parameters and for a subset of calculated parameters, as shown in the tables on *page 15* and *page 16*.

In addition to providing default reference range values for arterial samples, Siemens is providing tables that list reference range values for other sample types, which can be manually entered by system operators. Please see the tables in *Reference Ranges for Different Sample Types, page 16*. See *References, page 32*, for relevant citations.

The values provided for all the reference tables on the following pages derive from the technical literature. For a list of citations from the technical literature, see *References, page 32*. For guidance on defining site-specific reference ranges, refer to CLSI document EP28-A3c.[8]

Important Reference ranges 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.

Note The values in the *Default Reference Ranges: Arterial* table on the next page are also applicable to capillary samples, with the exception that limitations apply to pO_2 (see footnote c).

7. For instructions for manual entry of reference range values, see *Entering Critical Range Limits*, page 3; the same procedure is used to enter critical range and reference range values.
8. Clinical and Laboratory Standards Institute. *Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory; Approved Guideline* – Third Edition, Wayne, PA.: Clinical and Laboratory Standards Institute; 2010, CLSI Document EP28-A3c: Oct 2010.

Table 1: Default Reference Ranges: Arterial[9]

Parameter	Units/Alternate Units of Measurement	Reference Ranges
pH H^+	pH nmol/L	7.350–7.450[a] 44.7–35.5
pCO_2	mmHg kPa	32.0–48.0[b] 4.27–6.40
pO_2[c]	mmHg kPa	83.0–108.0[d] 11.07–14.40
Na^+	mmol/L	136.0–145.0
K^+	mmol/L	3.40–4.50
iCa^{++}	mmol/L mg/dL	1.15–1.33 4.6–5.3
Cl^-	mmol/L	98–107
Glu	mg/dL mmol/L	65–95[e] 3.6 –5.3
Lac	mmol/L mg/dL	0.36–0.75[f] 3.2–6.8
tHb	g/dL g/L mmol/L	12.0–17.5[g] 120–175 7.5–10.9
O_2Hb	% decimal	94.0–98.0 0.940–0.980
COHb	% decimal	0.5–1.5[h] 0.050–0.015
MetHb	% decimal	0.0–1.5 0.000–0.015
HHb	% decimal	0.0–5.0 0.000–0.050
nBili	mg/dL µmol/L	2.0–6.0 (neonate)[i] 34–103 (neonate)

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. Fasting, adult.
f. At bed rest, including female and male.
g. Gender specifics exist: Female 12.0 –16.0 g/dL, Male 13.5 –17.5 g/dL
h. Non-smokers.
For a light to medium smoker: 4.0–5.0%, Heavy smoker: 8.0–9.0%.
i. For a 0–1 day-old neonate. For adults the value is <2.0 mg/dL.
For the full range of nBili values that can be entered manually, see page 20.

9. The values in this table also apply to capillary sample with the exception of pO_2.
In an arterialized capillary sample, pO_2 may be unreliable.

Table 2: Default Reference Ranges: Arterial (Calculated Parameters)[10]

Calculated Parameter	Units/Alternate Units of Measurement	Reference Ranges
Hct	%	36 – 52[a]
	decimal	0.36 –0.52
HCO_3(act)	mmol/L	21.0 –28.0[b]
HCO_3(std)	mmol/L	21.0 –28.0[b]
BE(ecf)	mmol/L	-2.0 – +3.0
BE(B)	mmol/L	-2.0 – +3.0
sO_2	%	94.0 – 98.0[c]
	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. Gender specifics exist: Adult female 36 –47%, Adult male 40 –52%.

b. Plasma.

c. This is the range for adults. The range for newborns is: 40 – 90%.

Reference Ranges for Different Sample Types

Note Reference ranges are also known as “normal values”, “reference intervals” and “established ranges.”

As a convenience, Siemens is providing reference range tables for the whole blood sample types described below, as well as for pleural fluid. These tables show values that can be used until your facility establishes reference range values that are based on site-specific patient populations.

- For arterial and capillary sample reference values, see the tables in the previous section, *Default Reference Ranges for Arterial Samples, page 14*. As explained in that section, arterial reference range values are entered as default values for users who receive new instruments with the V5.1/5.1.1 release.

  Note With the exception of pO_2, capillary result values are identical to arterial result values, and the values in the default arterial table can be used.
- For reference range values for venous, mixed venous, pleural fluid, nBili sample, and neonatal arterial samples types, see the tables on the following pages.

10. The values in this table also apply to capillary samples.

The values in the reference tables on the following and preceding pages derive from the technical literature. For a list of literature citations, see *References, page 32*. For guidance on defining site-specific reference ranges, refer to CLSI document EP28-A3c.[11]

Important Reference ranges 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.

Important With the exception of pleural fluid pH, whole blood is used for all sample types in the following tables. "Sample type," in the context of the RAPIDPoint 500e system, does not refer to the constituent elements of whole blood but rather to the source from which the blood has been drawn, for example, the arteries or veins, or to the device used, as is the case for capillary samples. All testing for whole blood samples is performed in an identical fashion by the RAPIDPoint 500e system.

Note For instructions for manual entry of reference range values, see *Entering Critical Range Limits, page 3*; the same procedure is used to enter critical range and reference range values.

11. Clinical and Laboratory Standards Institute. *Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory; Approved Guideline* – Third Edition, Wayne, PA.: Clinical and Laboratory Standards Institute; 2010, CLSI Document EP28-A3c: Oct 2010.

Table 3: Reference Ranges: Venous[12]

Parameter	Units/Alternate Units of Measurement	Reference Ranges
pH H^+	pH nmol/L	7.320–7.430[a] 47.9–37.2
pCO_2	mmHg kPa	38.0–54.0 [b] 5.07–7.20
pO_2	mmHg kPa	23.0–48.0[c] 3.07–6.40
Na^+	mmol/L	136.0–145.0
K^+	mmol/L	3.40–4.50
iCa^{++}	mmol/L mg/dL	1.15–1.33 4.6–5.3
Cl^-	mmol/L	98–107
Glu	mg/dL mmol/L	65–95[d] 3.6–5.3
Lac	mmol/L mg/dL	0.56–1.39[e] 5.0–12.5[5]
tHb	g/dL g/L mmol/L	12.0–17.5[f] 120–175 7.5–10.9
O_2Hb	% decimal	~< 80.0% may be variable <0.800
COHb	% decimal	0.5–1.5 (non-smoker)[g] 0.000–0.015
MetHb	% decimal	0.5–1.5 0.000–0.015
HHb	% decimal	~>20.0% may be variable >200.0
nBili	mg/dL µmol/L	2.0–6.0 (neonate)[h] 34–103 (neonate)

a. Includes children and adults < 60 years; venous at 37°C.
b. Includes female and male adults.
c. Includes from 2 days to 60 years.
d. Fasting, adult.
e. At bed rest, including female and male.
f. Gender specifics exist: Female 12.0 –16.0 g/dL, Male 13.5 –17.5 g/dL.
g. Non-smokers.
For a light to medium smoker: 4.0–5.0%, Heavy smoker: 8.0–9.0%.
h. For a 0–1 day-old neonate. For adults the value is <2.0 mg/dL.
For the full range of nBili values that can be entered manually, see page 20.

12. The values in this table are not default values and can only be entered manually.

Table 4: Reference Ranges: Venous (Calculated Parameters)[13]

Parameter Calculated	Units/Alternate Units of Measurement	Reference Ranges
Hct	%	36 – 52[a]
	decimal	0.36 –0.52
HCO_3(act)	mmol/L	22.0 –29.0[b]
HCO_3(std)	mmol/L	22.0 –29.0
BE(ecf)	mmol/L	-2.0 – +3.0
BE(B)	mmol/L	-2.0 – +3.0
sO_2	%	60.0–85.0[c]
	decimal	0.600 –0.850
AnGap	mmol/L	10.0–18.0 using equation (Na + K)-(Cl + HCO_3)
$ctCO_2$	mmol/L	22.0–26.0

a. Adult, includes female and male.

b. plasma.

c. Adult, newborns range = 40 – 90%.

Table 5: Reference Ranges: Mixed Venous[12]

Parameter	Units/Alternate Units of Measurement	Reference Ranges
pO_2	mmHg	35.0–45.0
	kPa	4.67– 6.00
tHb	g/dL	12.0– 17.5
	g/L	120– 175
	mmol/L	7.5– 10.9

13. The values in this table are not default values and can only be entered manually.

Table 6: Reference Ranges: nBili (Premature)[14]

Units/Alternate Units of Measurement	Reference Ranges		
	0–1 Day	1–2 days	3–5 days
mg/dL	<8.0	6.0–12.0	10.0–14.0
µmol/L	<137	103–205	171–239

Table 7: Reference Ranges: nBili (Full Term)[13]

Units/Alternate Units of Measurement	Reference Ranges				
	Birth	1 hour	0–1 day	1–2 days	3–5 days
mg/dL	<6.0	<6.0	2.0–6.0	6.0–10.0	4.0–8.0
µmol/L	<103	<103	34–103	103–171	68–137

Table 8: Reference Ranges: Pleural Fluid pH[13]

Parameter		Reference Ranges
pH	transudates	7.400– 7.500
	exudates	7.350– 7.450
	H^+ transudates	39.8– 31.6
	H^+ exudates	44.7– 35.5

14. The values in this table are not default values and can only be entered manually.

Table 9: Reference Ranges: Neonatal Arterial[15]

Parameter	Units/Alternate Units of Measurement	Reference Ranges[a]	
		At Birth	0-1 Days
pH H^+	pH nmol/L	7.110–7.360 77.6–43.7	
pCO_2	mmHg kPa	27.0–40.0 3.60–6.40	
pO_2	mmHg kPa	8.0–24.0 1.07–3.20	
Na^+	mmol/L	133–146	
K^+	mmol/L	3.7–5.9	
iCa^{++}	mmol/L mg/dL		1.08–1.28 4.3–5.1
Cl^-	mmol/L	98–113	
Glu	mg/dL mmol/L		40–60 2.2 –3.3
Lac	mmol/L mg/dL	0.00–0.30 0.0–2.7	
tHb	g/dL g/L mmol/L	14.5–22.5 145–225 9.0–14.0	
O_2Hb	% decimal	~94.0–98.0[b] ~0.940–0.980	
COHb	% decimal	0.5–1.5 0.005–0.015	
MetHb	% decimal	0.0–1.5 0.000–0.015	
HHb	% decimal	0.0–5.0 0.000–0.050	

a. **Important**: The values in this table also apply to capillary samples with the exception of pO_2 results in an arterialized capillary, which may be unreliable.

b. Result may be variable.

15. The values in this table are not default values and can only be entered manually.

Table 10: Reference Ranges: Neonatal Arterial (Calculated Parameters)[16]

Calculated Parameter	Units/Alternate Units of Measurement	At Birth
Hct	%	36 – 52
	decimal	0.36 –0.52
HCO_3(act)	mmol/L	17.2 –23.6
HCO_3(std)	mmol/L	17.2 –23.6
BE(ecf)	mmol/L	-10.0 – -2.0
BE(B)	mmol/L	-10.0 – -2.0
sO_2	%	40.0 – 90.0
	decimal	0.400 – 0.900
AnGap	mmol/L	10.0–18.0 using equation (Na + K)-(Cl + HCO_3)
$ctCO_2$	mmol/L	13.0 –22.0

16. The values in this table are not default values and can only be entered manually.

EQA Sample Option

Note External Quality Assurance testing (EQA) is also known as "proficiency testing."

With this release, EQA[17] testing is simplified by introducing the following RAPIDPoint 500e features: (1) pressing a single EQA sample type button, enables an operator to enforce the multiple settings necessary to run EQA tests; (2) pressing a single button returns the instrument to normal testing, and (3) operators are required to confirm either that they want to continue or discontinue EQA testing at the beginning of each test, which supports the integrity of EQA testing. In addition, EQA-specific demographics, such as **Kit Identifier** and **Specimen ID** can be entered in the RAPIDPoint 500e system during analysis to better track EQA testing.

The **EQA Sample** type button, shown below, displays adjacent to other sample types icons at the **Analysis** screen, and is always available.

EQA Testing Considerations

We recommend that the following points be considered when running EQA samples:

- Follow the recommendations provided by the manufacturer of the EQA/Proficiency testing materials that you use for testing.
- Follow the instructions that are included in the EQA kit you have selected.
- Prior to EQA testing, run QC or AQC and then perform a 2-point or full calibration. After completion of all EQA samples, perform an additional 2-point or full calibration.
- Use cartridges that have been used recently to test whole blood. Cartridges used to measure whole blood samples may be less subject to the occurrence of micro-bubbles.
- EQA samples can be aspirated from syringes or directly from ampules. We recommend using the single-use, disposable Proficiency Survey Quick Adapter for aspiration from ampules.
- Copy trace log and sensor data after EQA testing is completed in case troubleshooting is required later.
- By using the **Reject Reason** notification feature, EQA samples can be indicated as rejected in the patient database. See *page 10*.
- During EQA testing, barcode entry can only be used for **Operator ID**.

17. A different type of EQA is used to evaluate the performance of operators across different sites. EQA in the context of these release notes refers only to the evaluation of test instruments.

Procedure

1. In **Setup**, select the parameters or custom panels for which you want to run EQA testing.
2. At the **System** screen, select **Setup** > **Sample** > **EQA Demographics**.
3. Select the EQA demographics that are applicable for your EQA testing, from the following:
   - **Kit Identifier**
   - **Specimen ID**
   - **Operator ID**
   - **Comment**
4. To require entry of a demographic, select the **Required** icon button (arrow) which displays next to each demographic.
5. Select the **Continue** button 3 times to return to the **Analysis** screen.

   Proceed to test an EQA sample, by following the steps below.
6. At the **Analysis** screen, select the **EQA Sample** type button.

   The **EQA Sample** type button is always available.

   When selected, the following actions automatically take place:
   - Correlation coefficients and AMR are turned off, and **Display Question Result** is turned on.

   Note After the test, correlation coefficients, AMR, and **Display Question Result** are automatically reverted back to their settings prior to the EQA test.
7. When the **Continue** button is selected to initiate analysis, the following message displays in a dialogue pop-up window:

   EQA Sample Option is selected.

   Touch **Yes** to select the EQA Sample Test.

   Touch **No** to return to the **Analysis** screen.
8. To continue with EQA testing, select **Yes,** and select the **EQA** sample type button.

   To return to normal testing, select **No**.
9. Repeat steps 6 to 8 until EQA testing is complete.

EQA Results in Printed Reports, when Sent to the LIS, and at the Recall Screen

In printed reports, EQA results are indicated by **EQA SAMPLE**, and EQA demographics that have been entered for the **Kit Identifier**, the **Specimen ID**, and the **Operator ID** display below **EQA SAMPLE** at the top of the report, while a **Comment**, if entered, displays at the bottom of the list of results.

EQA results at the **Recall** screen are indicated by **EQA** in the **Sample Type** column, where it follows the date and time entries. The entry overlaps the **Patient ID** field, which is always empty for EQA samples.

When sent to POCcelerator or another LIS, an EQA result is indicated as an **Analyzer EQA** sample (for more information, see chapter 3 of the *RAPIDPoint 500e Blood Gas System Interface Specifications Manual*).

Any Time Software Updates using the teamplay Fleet Application

Note A security level of 1 is required to use this feature.

With the V5.1/5.1.1 release, authorized teamplay Fleet[18] operators can install software remotely as soon as it is available. Until now, software has been distributed in physical upgrade kits. This new capability of electronic install kit distribution is available for RAPIDPoint 500e software releases beginning with the V5.1/5.1.1 release.

Installing software upon availability ensures RAPIDPoint 500e systems are running the latest security updates and enhances system functionality by providing new analyzer features as soon as they are available.

In addition to enabling remote software upgrade installation, and providing access to documentation related to the upgrade, teamplay Fleet provides the capability for your site to electronically monitor Siemens equipment performance and maintenance 24/7, simplifies requests for service support, and provides service metrics.

Note Siemens customers can register with teamplay Fleet without cost. See *page 27* for registration instructions, as well as for instructions on using the teamplay Fleet site to install new software.

Useful Background Information

- As explained in the instructions in the teamplay Fleet site, the install process requires the user to scan a QR code at the RAPIDPoint 500e **Confirm Software Installation** screen, and then enter a 6-digit code that teamplay Fleet provides into the confirmation code field on the same screen. This notifies Siemens that the installation has been completed.

  If the software from teamplay Fleet has been updated in the RAPIDPoint 500e system but the QR code has not been scanned and the confirmation code has not been entered, the system provides customers with the following two reminders until the QR Code is scanned and the confirmation code is entered:

  - A pop-up message displays at approximately noon each day to remind the operator that activation of the new software requires entry of a confirmation code (this also displays upon instrument reboot).
  - A 2D barcode icon displays in the banner of the screen.

  The current software will continue to operate as usual until the new software update is registered as completed. Both reminders disappear when the confirmation code is entered.

18. Availability varies by country. Contact your local Siemens representative for more information.

- Instructions for accessing download and install procedures for new software are provided on *page 27*. For additional information about uploading software to the RAPIDPoint 500e system, see chapter 7 of the *RAPIDPoint 500e Blood Gas System Operator's Guide*.
- Educational materials are available at the teamplay Fleet site by accessing the **Dashboard** page by using this link: https://fleet.siemens-healthineers.com, selecting the **Need Help?** box at the bottom-right of the screen, typing "update" in the question field, and selecting relevant update information from the list of "update" related documents that display.

Procedure

Note Software upgrades can take up to 2 hours to load into the RAPIDPoint 500e system.

1. If your site has not already registered to use teamplay Fleet, go to the following site to register: https://fleet.siemens-healthineers.com

   Select **Register**, and follow the instructions that display on-screen to complete the registration.

2. To receive alert notifications about new software updates, a teamplay Fleet user must be assigned the "Receive Update" role by the teamplay Fleet coordinators in their country or region. To obtain role authorization:
   a. Open this link: https://fleet.siemens-healthineers.com, which takes you to the **Dashboard** screen.
   b. Select the email icon from the top-right of the **Dashboard** screen.
   c. Email the contact who is indicated for your country or region to request authorization to receive update notifications and install new software.
3. To determine if new software is available:
   a. Open this link: https://fleet.siemens-healthineers.com.

      On the right-side of the menu bar on the **Dashboard** page, a bell icon displays at the top-right of the screen. If one or more notifications are available, a number will display in the bell.
   b. If a notification is indicated, select the bell icon.

      A page opens which displays notification information.
   c. If a software update is indicated at this page, record the information about the software upgrade, which you may need to enter later during the download and install process.

4. To access instructions to upload and install the new software, follow these steps:
   a. Open this link: https://fleet.siemens-healthineers.com.
   b. The teamplay Fleet application opens to the **My Dashboard** page.
   c. Select **Systems Update** tab from the menu.
   d. Locate and select the RAPIDPoint 500e software update named “xxxx.xxx” and select it (“xxxx.xxx” represents the update you wish to install).
   e. After selecting the RAPIDPoint 500e update a sub-menu displays that shows download and installation instructions.
   f. Follow the instructions that are provided to download and install the software upgrade.

      After you enter the confirmation code, the new software will be available for use on your RAPIDPoint 500e system.

Note For teamplay Fleet support, go to https://fleet.siemens-healthineers.com and select the email icon (an envelope), which opens to a page that displays teamplay Fleet contact information.

Patient Demographics Sources Feature

Explanation of Patient Demographics Sources Options

The **Patient Demographics Sources** screen provides the following four button-selectable options:

- **RAPIDPoint® 500e**
- **LIS Communications**
- **RAPIDPoint® 500e, LIS Communications**
- **LIS Communications, RAPIDPoint® 500e**

Note For the 3 options that use the LIS, **LIS Communications** must be enabled in Setup to use this option (select **Setup** > **Printers and Devices** > **Communications** > **LIS Communications**).

Procedure

1. At the System screen, select **Setup** > **Sample** > **Patient Demographics**.
2. If not already selected, select **Patient ID** and any additional patient demographics as needed.
3. Select **Patient Demographics Sources**:
4. Select one of the following:
   - **RAPIDPoint® 500e**

     A search for Patient data is performed only in the RAPIDPoint 500e local database for demographics data field entry.
   - **LIS Communications**

     Patient data is sought only in POCcelerator or another LIS for demographics data field entry.

     CAUTION Patient demographics data may be lost or blanked if this option is used and the LIS is unable to provide requested demographic data. See *Caution Message, page 30* for more information.
   - **RAPIDPoint® 500e, LIS Communications**

     First, the RAPIDPoint 500e local database is searched for patient demographics data. If data is not found in the RAPIDPoint 500e local database, a search is performed in POCcelerator or another LIS database.
   - **LIS Communications, RAPIDPoint® 500e**

     First, POCcelerator or another LIS, database is searched first for patient demographics data. If patient demographics data is not found, a search is performed in the RAPIDPoint 500e local database.

5. Select the **Continue** button.

Caution Message

When **LIS Communications** (only) is selected, the following message displays:

> CAUTION: Disabling patient demographic search of RAPIDPoint 500e® database may cause data from previous samples to be edited or blanked. Are you sure you want to do this?
>
> Touch **Yes** to save the change.
>
> Touch **No** to cancel.

If you touch **Yes**, the changes are saved, and you are returned to the **Patient Demographics** screen. If you touch **No**, settings are not saved and you remain at the current screen.

Explanation of Patient Data Blanking and Data Editing

When **LIS Communications** is selected, if patient demographics data cannot be retrieved from the LIS, either because a problem exists with the LIS connection or because the patient demographics data has not been entered in the LIS, then the corresponding demographics data field in the RAPIDPoint 500e system will be blanked.

If a patient demographics data field has been blanked as a result of selecting the **LIS Communications** option when demographics data could not be retrieved from the LIS, the message “Report Data edited” will display in a printout for any earlier sample(s) associated with the same Patient ID. This indicates simply that the data for the earlier sample has been modified or blanked.

Microsoft Operating System

Updates to the Microsoft Operating System used in the RAPIDPoint 500e system have been implemented. For further information, contact your local technical support distributor. See *Technical Assistance* section on *page 33*.

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Base 64 Encoder
base64.cpp and base64.h
base64 encoding and decoding with C++.
More information at https://renenyffenegger.ch/notes/development/Base64/Encoding-and-decoding-base-64-with-cpp
Version: 2.rc.04 (release candidate)
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Technical Assistance

For technical assistance contact your local technical support provider. For customer service or additional information contact your local technical support distributor.

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