Proxima

*pH on Proxima*

**Operating principles**

The Proxima Sensor is fabricated as a single multi-analyte chip that carries an array of individual sensors, each of which measures a different analyte.

pH in Proxima is measured by direct potentiometry.

**Measuring and Reference ranges**

<table>
<thead>
<tr>
<th>Analyte</th>
<th>Units*</th>
<th>Measuring range</th>
<th>Resolution</th>
<th>Reference range (arterial)</th>
</tr>
</thead>
<tbody>
<tr>
<td>pH</td>
<td>pH</td>
<td>6.800-7.800</td>
<td>0.001</td>
<td>7.35-7.45(1)</td>
</tr>
<tr>
<td>nmol/l</td>
<td>158.4-15.8</td>
<td>0.1</td>
<td>44.6-35.4</td>
<td></td>
</tr>
</tbody>
</table>

*The Proxima System can be configured with any of these units*

Each institution should establish its own reference range for diagnostic evaluation of patient results. It is recommended to use reference ranges for the population being tested.

**Clinical significance** *(2)*

The pH of arterial blood is normally kept within a narrow range around pH 7.4 by the buffer systems in the blood (bicarbonate, phosphate and proteins) closely controlled by respiratory and metabolic mechanisms.

Many pathological conditions are accompanied by disturbances of the acid-base balance of the blood and measurement of blood pH is an important component in the determination of these disorders.

**Arterial blood pH of less than 7.35** is termed acidosis, which may have either respiratory or metabolic primary causes. **Respiratory acidosis** is caused by conditions that decrease elimination of carbon
dioxide through respiration, leading to a decrease in blood pH. These conditions include:

1. Factors that depress the respiratory centre, such as narcotics and barbiturates as well as impairment of the central nervous system by trauma, infection or degenerative disorders.
2. Conditions that affect the respiratory apparatus, such as airway obstruction, chronic obstructive pulmonary disease, severe pulmonary infection or respiratory distress syndrome.

Metabolic acidosis may be caused by a range of factors including:

1. Accumulation of organic acids in conditions such as lactic acidosis, diabetic acidosis or toxicity from methanol, or ethylene glycol.
2. Reduction in the excretion of inorganic acids due to renal failure.
3. Excessive loss of bicarbonate due to gastrointestinal fluid loss from diarrhoea or pancreatitis, or due to increased renal excretion (decreased tubular reclamation).

Arterial blood pH of greater than 7.45 is termed alkalosis, which may have either respiratory or metabolic primary causes. Respiratory alkalosis is caused by conditions that increase the elimination of carbon dioxide through rapid respiration, leading to an increase in blood pH. These conditions include:

1. Non-pulmonary stimulation of the respiratory centre e.g. due to hypoxia, therapeutics such as salicylates and catecholamine’s, anxiety or gram negative septicaemia.
2. Pulmonary disorders including pulmonary embolism, atrial shunt and congestive heart failure (severe stages may cause acidosis).
3. Ventilator induced hyperventilation.

The usual primary causes of a metabolic alkalosis are:
**Proxima**

**pH on Proxima**

1. Excessive vomiting, leading to a significant loss of acids from the system.
2. Iatrogenic factors including antacids, bicarbonate containing intravenous fluids and sodium citrate overload from massive blood transfusion.

**Measurement Temperature**

pH is a temperature-dependent quantity and the Proxima measures and reports pH at 37°C.

**Performance Data**

These are example performance data given in the tables below.

**Precision data in controls:**

Two different levels of quality control material were estimated using a minimum of 6 Proxima Systems over a minimum of 27 days.

<table>
<thead>
<tr>
<th>Precision data (pH)</th>
<th>N</th>
<th>Mean</th>
<th>SD*</th>
<th>%CV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level 1</td>
<td>225</td>
<td>6.813</td>
<td>0.016</td>
<td>0.23</td>
</tr>
<tr>
<td>Level 2</td>
<td>212</td>
<td>7.413</td>
<td>0.015</td>
<td>0.20</td>
</tr>
</tbody>
</table>

*Based on total SD

**Method comparison data**

The study was conducted in a laboratory setting with transfusion blood samples. Arterial blood samples were collected and compared with the Siemens 1200 reference device.

<table>
<thead>
<tr>
<th>pH (pH units)</th>
<th>N</th>
<th>Slope</th>
<th>Intercept</th>
<th>RMSE*</th>
<th>R²</th>
<th>Min</th>
<th>Max</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>586</td>
<td>1.002</td>
<td>-0.008</td>
<td>0.022</td>
<td>0.99</td>
<td>6.802</td>
<td>7.752</td>
</tr>
</tbody>
</table>

*RMSE: Root mean square error
Factors affecting the results

Adequate sample should be drawn to ensure a representative arterial blood sample is measured.

As Proxima operates in a closed system the arterial blood sample couldn’t be exposed to air if the Proxima Sensor is used following the Proxima User Manual.

pH on the sample is measured on the Proxima Sensor within less than 1 min ensuring the prompt analysis of the sample.

Potential interference by exogenous and endogenous substances studies (based on CLSI guideline EP7 –A2 “Interference Testing in Clinical Chemistry; Approved Guideline-Second Edition”) have demonstrated the specificity of the pH measurement on the Proxima Sensor.

References