

**EN CueSee® Hyperbaric**

**Intended use**

CueSee® Hyperbaric is an assayed, quality control material for professional use in the verification of the precision and accuracy of the critically high pO<sub>2</sub> value range of many blood gas analyzers.

**Summary and principle**

CueSee® Hyperbaric is available at one level with a known pO<sub>2</sub> value in the critically high pO<sub>2</sub> value range. It is intended that CueSee® Hyperbaric should be used in the periodic verification of the precision and accuracy of blood gas analyzers.

**Contents**

CueSee® Hyperbaric provides one level in the critically high pO<sub>2</sub> value range, each ampule holding 2.5 mL of solution. CueSee® Hyperbaric is prepared using pure salts in a physiologically buffered aqueous solution. Tonometry with a predetermined level of oxygen balanced with nitrogen and different salt concentrations provides the distinct assay value for measurement of partial pressure of oxygen. CueSee® Hyperbaric contains no preservatives, viscosity adjusters or other additives that might adversely affect electrode measurements.

**Storage and stability**

CueSee® Hyperbaric should be stored at a temperature of 2–30 °C (36–86 °F). Stored unopened at this temperature the product is stable as indicated until the expiration date on the ampules and the outer box. After opening an ampule of CueSee® Hyperbaric, the product is stable for 30 seconds.

**Procedure**

1. Remove the ampule from box and tray. Equilibrate the ampule for a minimum of 1 hour to the room temperature where the testing will take place. Note the current room temperature.
2. Immediately before use, placing the ampule between the thumb and index finger, shake the ampule vigorously for at least fifteen seconds to re-equilibrate the gases with the solution.
3. Swirl the ampule gently to return liquid to the bottom. Allow bubbles to rise to the surface before opening the ampule.
4. Protect fingers with gauze, tissue or gloves.
5. **The One Point Cut (OPC) ampule must be opened as illustrated below.**
6. Using techniques described in the instrument manufacturer's system manual, transfer the sample from the ampule to the card, cartridge or analyzer within 30 seconds after opening of the ampule. Gently load the sample from the syringe to test cartridge/card following the sampling procedure of the instrument operating instructions. **Important: Use of the Quality Control or Calibration Verification Mode, depending on instrument manufacturer, may be needed to obtain high pO<sub>2</sub> results.**
7. **For i-STAT® instruments, read the pO<sub>2</sub> target range from the Eurotrol Value Assignment Sheet according to the corresponding room temperature. For epoc® System users, refer to assigned values at [www.siemens.com/epoc](http://www.siemens.com/epoc).**
8. Refer to local, state and/or federal regulations or accreditation requirements for frequency of use.

**Warnings and precautions**

1. For in vitro diagnostic use only.
2. This product should not be disposed of in general waste. Consult local environmental authorities for proper disposal.
3. Each ampule is singly use only.
4. Caution: US Federal law restricts this device to sale by or on the order of a licensed practitioner.

**Expected values**

**i-STAT® analyzer**

The Eurotrol assigned values for the i-STAT® analyzer have been obtained after equilibration of randomly selected ampules from the applicable batch at 25 ± 1 °C before measurement and have been measured on multiple i-STAT® analyzers using multiple types of cartridges. The expected pO<sub>2</sub> value for your applicable incubation temperature is shown in the value sheet which can be found on [www.eurotrol.com/documents](http://www.eurotrol.com/documents).

**Epoc® system**

The assigned values for the epoc® System have been obtained after equilibration of randomly selected ampules from the applicable batch at 22 ± 1°C before measurement and have been measured on multiple epoc® readers using multiple lots of cards. The assigned values can be found at [www.siemens.com/epoc](http://www.siemens.com/epoc). Refer to the epoc® System Manual for more information on target adjustments for variable ambient temperature and barometric pressure.

**Limitations**

- The pO<sub>2</sub> values of CueSee® Hyperbaric vary inversely with temperature changes. To obtain a high degree of correlation with the assigned values the ampules should be equilibrated to 22 °C (71.6 °F) for the epoc® System and to 25 °C (77 °F) for the i-STAT® analyzer.
- The ranges of the product are intended only as guidelines and laboratories should determine the ranges based on their own test system and tolerance limits.
- The assigned values are applicable at sea level and with the applicable cartridge types and cartridge lots only.
- CueSee® Hyperbaric is very sensitive to contamination once opened. When sampling the fluid within 30 seconds, the error is less than 2%, based on open ampule testing.
- CueSee® Hyperbaric is not to be used as a calibrator.
- Incorrect sampling, storage, or other mishandling may cause the readings to deviate from the target values.

For further information and/or technical assistance, please contact:



**Manufacturer**

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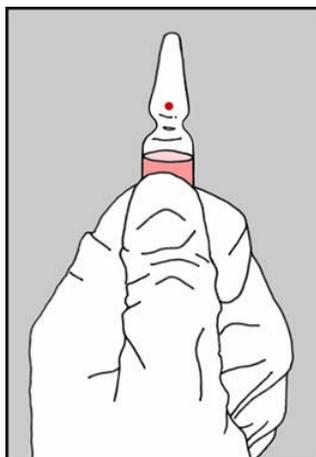
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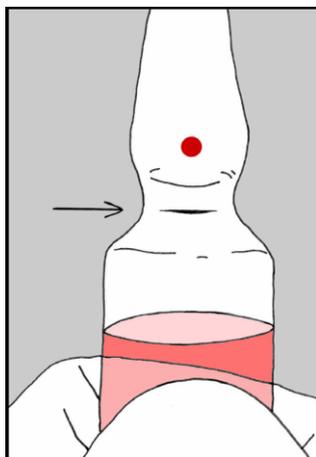
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**Symbols used**

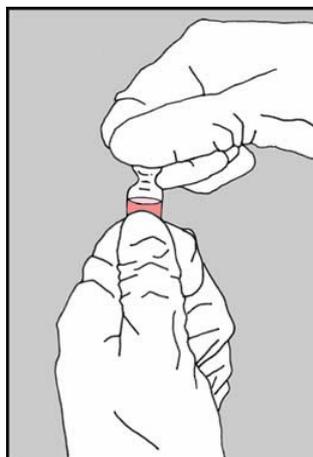
	Use-by date		Batch code
	In vitro Diagnostic Medical Device		Temperature limit
	Manufacturer		Catalogue number
	Control		Do not re-use
	Prescription use only		Consult instructions for use
			Date of manufacture



Hold the bottom of the ampule with thumb pointing to the red colored dot.



Cut located below the red dot is the breaking point of the ampule.



Grasp the top of the ampule with other hand, positioning thumb at the red dot.



Press back to break at the cut under the red dot.