



 Kit 740004  
 High 740304  
 Mid 740204  
 Low 740104



Exp: 2009-05  
 Exp: 2009-05  
 Exp: 2009-05  
 Exp: 2009-05



For In Vitro  
Diagnostic  
Use



0034091.000

INTENDED USE

WATERS MEDICAL SYSTEMS (WMS) liquid control is an assayed quality control material used for monitoring the performance of the Oxicom family of whole blood oximeters.

PRODUCT DESCRIPTION

WMS Liquid Controls are provided in three (3) levels (high, mid and low) for monitoring performance at significant points within the clinical range. WMS Liquid Controls are packaged in bottles, each containing 5.0 ml of solution. Each box contains nine (9) control bottles, three (3) of each high, mid and low. Active Ingredients:

Water, Viscosity Modifiers, Beads, Salts, Preservatives and Dyes.

**Contains no hemoglobin and no human or biological materials.**

STORAGE

The expiration date stated on the WMS liquid control packaging is for product stored at room temperature (2 - 30 °C). After opening, each bottle of control is stable for sixty (60) days stored at room temperature (2 - 30 °C). Bottles should be tightly closed after each use. Avoid exposing bottles to freezing and temperatures greater than 30 °C.

**Note:** The opened bottle date should be recorded on the bottle label and the product should be discarded 60 days after opening.

DIRECTIONS FOR USE

Controls are analyzed in the same manner as patient samples. Refer to the Oxicom operator's manual for complete instructions on how to analyze a sample. WMS Liquid Controls should be utilized weekly to evaluate Oxicom performance. Perform the following steps to fill the cuvette with WMS liquid control:

- Vigorously shake the bottle to obtain a uniform suspension, making certain there is no sediment in the bottom of the bottle. Allow the foam to settle; keep solution mixed.
- Using a 1 ml syringe, remove 0.5 ml of solution from bottle and fill the cuvette (with plug in place). Be sure to expel bubbles out of the cuvette.
- Gently agitate the sample between your hands.
- With the Oxicom in the operations mode (O<sub>2</sub> Saturation mode for Oxicom 3000s)
  - When the Oxicom in the RDY state, press the Start Button.
  - When INS is displayed, insert the Liquid Control filled cuvette into the sample chamber bottom insert down. DO NOT inject the liquid into the sample chamber.
  - Once the Oxicom has displayed the Sat value of the liquid control, record the value then remove the cuvette from the sample chamber.
  - Discard sample. DO NOT inject the liquid back into the bottle.
- Repeat steps 1 through 4 with each level of the liquid control.

After each use, wipe the top of the bottle, replace the cap, and immediately tighten. Do not use liquid controls after the expiration date printed on the bottles and box, or 60 days after the bottle open date recorded on each bottle label.







EXPECTED VALUES

The control values assigned to WMS liquid control are based on multiple determinations performed on randomly selected samples from each lot. The listing represents the expected range and mean value of this range. The expected values are provided as a guide in evaluating Oxicom performance. Since instrument design and operating conditions may vary, each laboratory should establish its own expected values and control limits. The mean value established should fall within the published expected value range and total imprecision less than 3%.

LIMITATIONS

- WMS Liquid Control is sensitive to many instrument related factors that would affect analytical results. Because it is not a blood-based material, it may not detect certain malfunctions that would affect the testing of blood.
- This product is intended for use as a quality control material and can assist in evaluating the performance of the Oxicom whole blood oximeter. It is not for use as a calibration standard and its use should not replace other aspects of a complete quality control program.








EXPECTED VALUES \*

Low		Mid		High	
 740104		 740204		 740304	
 Exp.: 2009-05		 Exp.: 2009-05		 Exp.: 2009-05	
O <sub>2</sub> SAT		O <sub>2</sub> SAT		O <sub>2</sub> SAT	
%		%		%	
Mean	Range	Mean	Range	Mean	Range
<b>Waters</b>					
Oxicom	55 48 - 62	71	64 - 78	86	79 - 93
2000, 2100, 3000					

\* expected range is defined as mean +/- 7% O<sub>2</sub>Sat.



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Waters Part Number	For In Vitro Diagnostic Use	Lot Number
		
Store at	Use By	Manufactured For
		
		Consult Instructions For Use