



## Instructions for Use Ozone in Water Test Strips K100-0111

### Indications for Use

The RPC E-Z Chek® Ozone in Water Test Strips (K100-0111) are designed to indicate the presence of ozone in water used in hemodialysis.

### **Procedure to detect (test for) ozone levels between 0 ppm and 0.4 ppm:**

- 1) Dip one test strip into a 50mL (about 2 oz.) water sample with constant, gentle back-and-forth motion for 10 seconds (25-28 strokes).
- 2) Remove the strip, shake once, briskly, to remove excess water and wait 20 seconds.
- 3) Then, view through the aperture pad to match with the closest color on the bottle label.
- 4) Complete color matching within 30 seconds.

Note: For better color matching view the aperture against a white surface. A suggestion is to fold the white plastic handle of the test strip under the aperture so that it produces a white viewing background (blocks distractions from behind aperture).

### **Procedure to detect (test for) ozone levels between 0.5 ppm and 1.0 ppm:**

- A) Collect a 25 ml sample of the ozonated water to be tested.
  - B) Dilute and mix the 25 ml ozonated test sample with 25 ml of known ozone-free water (distilled, D.I., or RO).
  - C) Immediately test the resulting solution using the K100-0111 ozone test strip and the instructions for use in 1-4 above.
  - D) Compare the color development on the test strip to the color blocks on the ozone test strip bottle.
  - E) Note the test result and multiply it times two (compensates for 50% dilution) to determine the actual ozone level.
- For example: If the ozone level in the initial 25 ml ozonated sample was actually 0.6 ppm, then the test value after 50% dilution should be 0.3 ppm. Record the actual ozone value as 0.6 ppm.

### **Warnings and Cautions**

- Do not touch the indicator pads.
- Keep all unused test strips in the original bottle.
- Replace cap immediately/tightly after removing a strip.
- Do not use test strips from an opened or unopened bottle after expiration date printed on the bottle label.
- Do not allow the test strip to come in contact with liquids or with work surfaces that may contaminate the strip.
- Do not leave test strips in areas exposed to vapors of any type.
- *Caution:* When used as a medical device, Federal Law restricts this device to sale by or on order of a physician.

### **Storage and Handling**

#### **KEEP THE CAP ON TIGHT BETWEEN USES. REPLACE CAP IMMEDIATELY AFTER REMOVING STRIP.**

Store at temperatures between 15°-30°C (59°-86°F). The lot number and expiration date are printed on each bottle. Do not use a test strip after the expiration date. Do not touch the indicator pad. Do not allow the test strip to come in contact with liquids or with work surfaces that may be contaminated with potentially interfering substances. Do not leave test strips in areas exposed to chlorine vapors or other oxidizing vapors.

#### **Important Note: RPC's Certi-Chek™ Field Verification Program:**

Customers purchasing test strips from RPC are required to adhere to all test strip instructions for use, including storage and handling requirements, but are not required to perform the test strip QC tests outlined in the individual test strip instructions for use as these tests are performed for the customer by RPC. Other manufacturers make some of the test strips distributed by RPC. These manufacturers are aware of, and endorse, the RPC policy of performing their test strip field QC tests for RPC customers.

A certificate of conformance for QC validation is available for each test strip type, by lot number. This certificate should be kept on file as proof for surveyors/inspectors – that test strip quality assurance is performed by RPC – when the dialysis center personnel have documentation proving that the strips were purchased from RPC. The certificate of conformance can be faxed to you, or you can download it from the RPC Web site at [www.rpc-rabrenco.com](http://www.rpc-rabrenco.com). You will need to know the RPC part number and lot number of the test strips for which you desire a certificate of conformance.