CHEMTEQ®

DG Indicator
Sterilization Strip
Chlorine Dioxide
PN: 570

Technical Summary

Application

The DG Chlorine Dioxide Indicator Strip (PN: 570) is a colorimetric indicator strip designed to provide real-time indication of chlorine dioxide gas. The indicator is suitable for sterilization applications

Specifications

a. Dimensions: 8cm (3.15in) x 0.5mm (0.02in)
b. Operating temperature: -20°C to 55°C (-4°F to 131°F)
c. Operating humidity: 5% RH to 85%RH
d. Optimum detectable limit: 900ppm·hr at 10 cm/sec face velocity
e. Color change: Beige to brown (PANTONE® 2324U)
f. Storage temperature: 4°C to 25°C, (39°F to 77°F)
g. Shelf life: 1 year at 4°C to 25°C, (39°F to 77°F)
h. Service life: 1 year

Cross interferences and limitations: Strong oxidizers produce similar color. No other interferences or limitations are known.

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Abbreviations
% *CV* = Coefficient of variance
|Bias| = Mean bias
AC = Overall accuracy
C = Concentration
*C*T* = Exposure Dose
D = Diffusion Coefficient
DGIS = DG Indicator Strip
M = Mass flux
NIOSH = National Institute of Occupational Safety and Health
OSHA = Occupational Safety and Health Administration
P = Pressure
PEL = Permissible exposure limit
ppm = Parts per million
T = Time
t_{abs} = Absolute temperature

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1. Test Protocol

The Chlorine Dioxide DG Indicator strip (DGIS) is tested following the Chemteq Protocol for Calibration and Evaluation of Monitors [1]. This protocol is based on the NIOSH Manual of Analytical Methods [2] and NIOSH Guidelines for Air Sampling and Analytical Method Development and Evaluation [3]. Seven factors were identified that could affect the performance of the DGIS and were investigated in this evaluation, namely: analyte concentrations, exposure time, face velocity, interchangeability, temperature, relative humidity, and cross interferences. In this protocol, all factors are investigated. Each test was conducted using two to four replicates per data point to account for potential variability in the results. The results were analyzed visually by two independent observers using PENTONE® colors [4]. A total of forty-two data points was collected. Twenty-five for calibration and seventeen for validation.

1.1. Analyte Concentration

Chlorine dioxide gas concentrations ranged from 200ppm to 3600ppm. Chlorine dioxide is generated using the sodium chlorite and sulfuric acid method and diluted with air.

1.2. Exposure Time

Exposure times ranged from five minutes to five hours

1.3. Face Velocity

Face velocity was kept between five and ten centimeters per second.

1.4. Interchangeability

In an ideal situation, the value of the exposure dose ($C*T$) should be the same, irrespective of the value of exposure time T and the analyte concentration C. In this protocol, the DGIS performance was investigated at low concentrations for long exposure times and at high concentrations for short exposure times.

1.5. Temperature

Exposure temperature affects diffusive monitors in two different ways: Diffusion coefficients (D) of gases and vapors are a function of absolute temperature (tabs) and pressure (P). The mass flux (M) is a function of D and C, whereas C is a function of P and T.

$$\boldsymbol{D = f\left[\frac{(t_{abs})^{\frac{2}{3}}}{P}\right]}$$

$$M = f(D, C)$$

$$M = f\left[(t_{abs})^{\frac{1}{2}}\right]$$

Therefore,

$$C = f\left(\frac{P}{t}\right)$$

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This inherited effect results in approximately 1% difference for every 6°C (10.8°F).
The kinetics of the chemical reaction between the sensor and the analyte are affected by temperature and has a significant effect on the performance of the DGIS at -20°C and 50°C.

1.6. Relative Humidity

The effect of relative humidity was tested between 5%RH to 85%RH.

1.7. Cross Interferences

The DGIS was exposed to at least four times the OSHA PEL of the following substances: Alcohols, aromatic hydrocarbons, carbon monoxide, chlorine, formaldehyde, glutaraldehyde, halogenated hydrocarbons, hydrogen chloride and nitrogen dioxide.

2. Calibration

The DGIS was calibrated at ambient conditions (temperatures between 22°C and 24°C, relative humidities between 55% RH and 65% RH and face velocities between five and ten centimeters per second). Chlorine dioxide concentrations; 200, 450, 600, 900, 1500, 1800 and 3600ppm. Exposure times ranged between 5 minutes and 5 hours. The calibration curve (Figure 1) is generated using twenty-five data points.

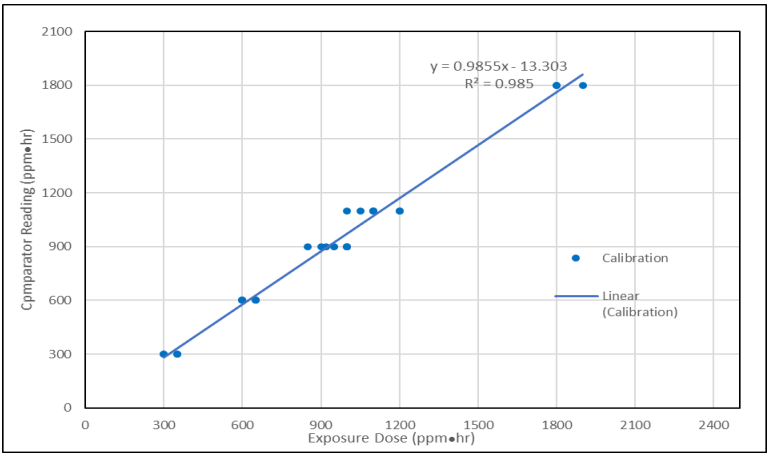

Figure 1: Calibration

3. Validation

3.1. Validation at Ambient Conditions

The performance of the DGIS was validated at ambient conditions and the results are depicted in figure 2 below. Statistical analysis of the results determined that the coefficient of variance (%*CV*) was 6.7%, with a mean bias (|Bias|) of 0.6% (figure 3). Based on Busch statistical protocol [5], the probabilistic overall accuracy (*AC*) of the DGIS was found to be ±14.0.

$$AC = \pm\left(2 \times CV + \left|Bias\right|\right)$$

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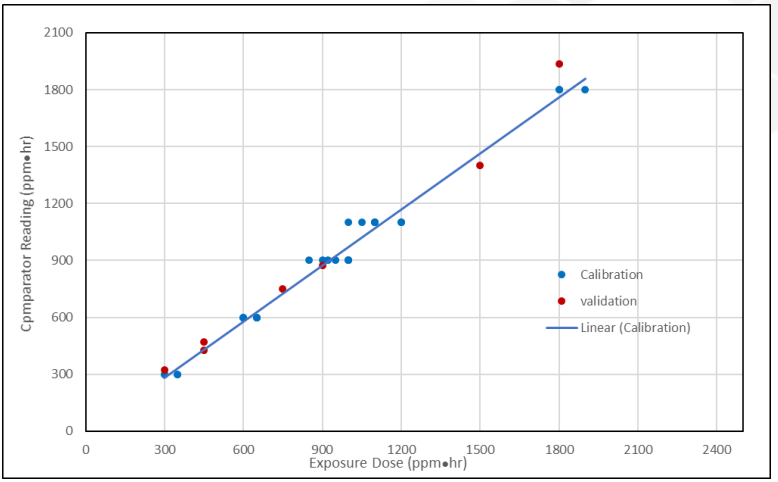

Figure 2: Validation

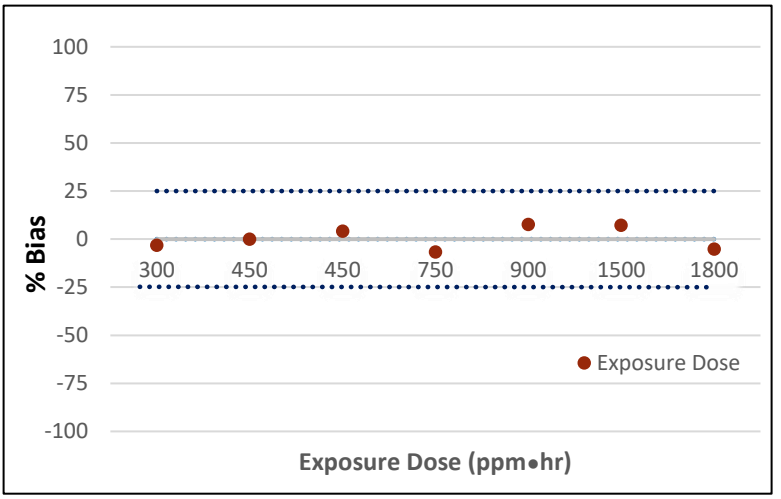

Figure 3: Bias

3.2. Interchangeability Effect

Figure 4 depicts the exposure of 900 ppm*hr. chlorine dioxide to the DGIS to evaluate the effect of interchangeability. The concentration of chlorine dioxide ranged from 200 – 3600 ppm, and exposure times ranged from 0.25 – 4.5 hours. The results indicate that interchangeability has no impact on the performance of the DGIS to chlorine dioxide.

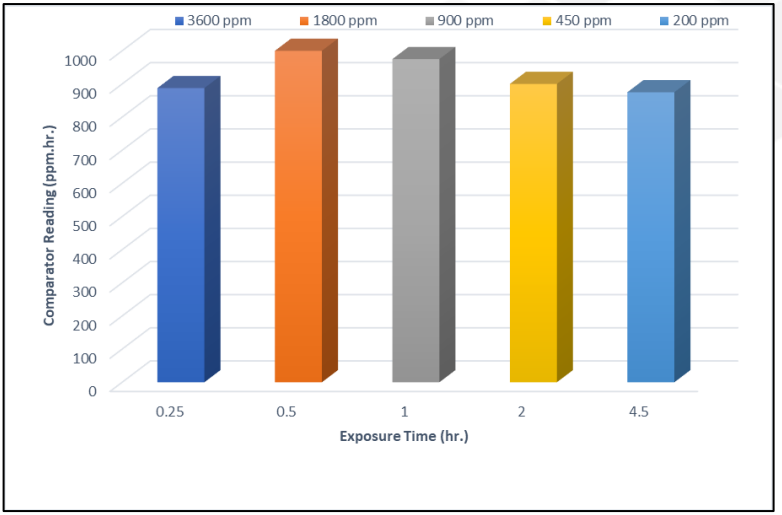

Figure 4: Interchangeability

3.3. Temperature Effect

The DGIS maintained a ±6% bias within 7°C and 32°C, and substantially greater bias at -19°C and 49°C with -48% and +19% respectively. The results are depicted in figure 5 below.

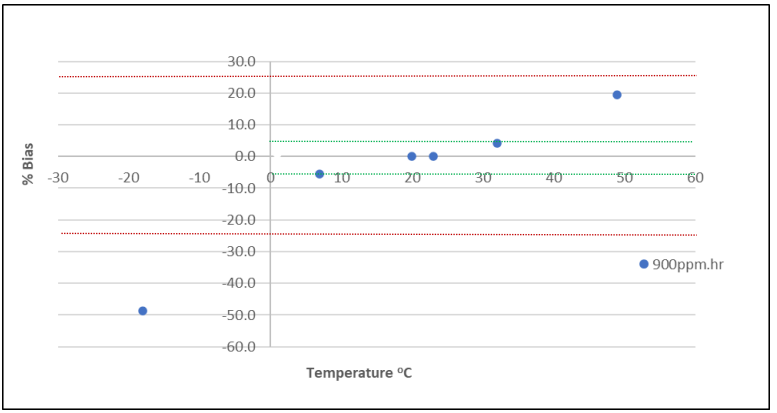

Figure 5: Temperature

3.4. Relative Humidity

Relative humidities between 5%RH and 85%RH have significant effect on the performance of the DGIS.

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3.5. Cross Interferences

The DGIS was exposed to atmospheres containing at least four times the OSHA PELs for the following substances: alcohols (methanol, ethanol, and isopropanol), aromatic hydrocarbons (benzene, toluene, and xylene), carbon monoxide, formaldehyde, glutaraldehyde, halogenated hydrocarbons (chloroform, methylene chloride and carbon tetrachloride), and hydrogen chloride. These substances showed no effect on the performance of the DGIS. High concentration (% levels) of chlorine produce a light brown color, Nitrogen dioxide produces a similar color to chlorine dioxide. No other interferences are known.

4. Conclusion

1. The chlorine dioxide DG Indictor strip responds well to chlorine dioxide gas under a wide range of concentrations, exposure times, humidities, and temperatures.
2. Under ambient condition, the DGIS has an overall accuracy of ± 14%.
3. Interchangeability has no effect on the performance of the DGIS.
4. Extreme temperatures produce significant biases. At 49°C and -19°C, the DGIS showed a bias of +19% and -48%, respectively.
5. The chlorine dioxide DG Indictor Strip produced repeatable, uniform, and consistent colors when exposed to chlorine dioxide (figure 6).
6. The overall performance of the DG Indicator Strip makes this device an ideal chlorine dioxide sterilization indicator.

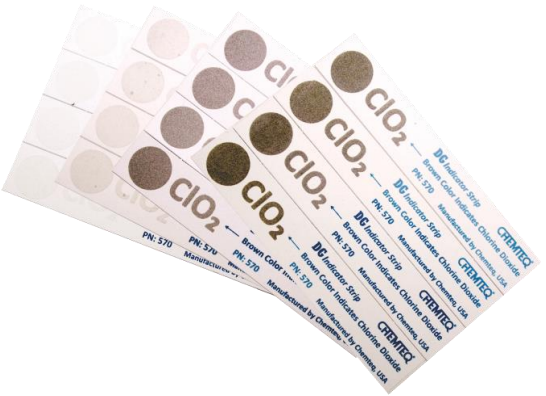

Figure 6: DG Indicator Strip

5. References

1. Chemteq Protocol for Calibration and Evaluation of Monitors, DD-917-0004-050612 A (2012).
2. NIOSH Manual of Analytical Methods, 4th Ed., Eller, P.M., ed., U.S. *DHHS* Publication No. 94-113, Cincinnati (1994).
3. KENNEDY, E.R., FISCHBACH, T.J., SONG, R., ELLER, P.M., and SHULMAN, S.A., Guidelines for Air Sampling and Analytical Method Development and Evaluation, DHHS *(NIOSH)* Publication No. 95-117, Cincinnati (1995).
4. PENTONE® uncoated and coated colors (1HJ40223A0100GKK20 and 1SVNB23R002203VM20)
5. BUSCH, K.A., SCP Statistical Protocol, in: Documentation of the NIOSH Validation Tests, Taylor, D.G., Kupel, R.E., and Bryant, J.M., eds., Pub. No. 77-185, *DHEW (NIOSH),* Cincinnati (1977).