

## Dry Eye Testing Lacks Standardization

- 4.8 million Americans affected by Dry Eye (DE) disease <sup>1</sup>
- DE caused by tear production deficiency or excessive tear evaporation <sup>2</sup>
- DE research limited by lack of:
  - Consensus on diagnostic criteria and tests that define DE
  - Control of ambient conditions affecting DE test results
- Low-humidity environment induces DE symptoms useful to DE research
- Current method:
  - Costs up to \$2 million
  - Has limited locations
  - Exposes entire body to adverse conditions

**Mission: To create a low-cost, portable device that controls the relative humidity around the eye while recording blink rate, providing a standardized environment for clinical and diagnostic DE testing.**

### Design Criteria

Control Relative Humidity (RH)	15 - 40% ± 3%
Monitor Blink Rate	errors ≤ 5%
Manufacturing Cost	< \$1,000
Goggle Weight	< 0.45 kg
Conditioning Pack Weight	< 2 kg
Set-up Time	< 10 min

## CTGS Achieves Desiccating Environment and Increases Dry Eye Severity

### Device Evaluation

Tests were performed to evaluate the ability of the CTGS to create a localized desiccating environment.

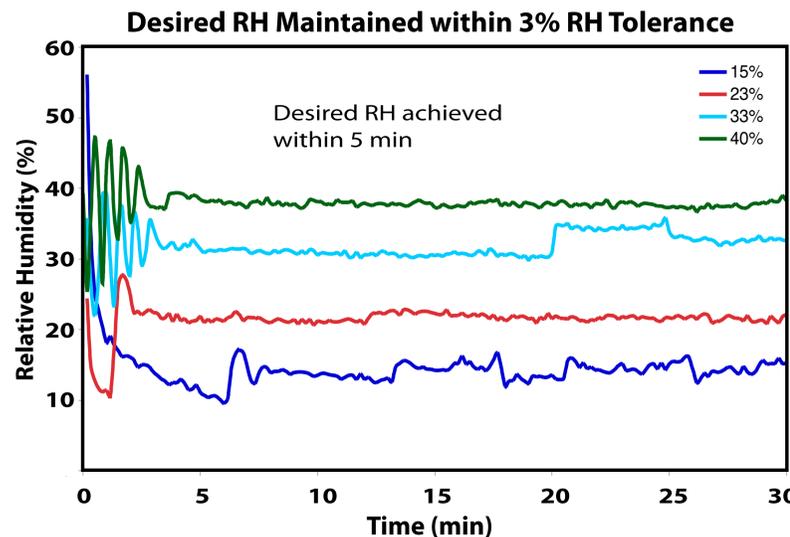


Figure 1. RH in the goggles with desired RH set at 15, 23, 33, and 40% RH.

### Clinical Evaluation

Ocular tests before and after CTGS use:

- Visual acuity
- Fluorescein tear film breakup time
- **Corneal topography (SRI) [Fig. 2]**
- Kinetic topography (tear film stability)
- Tear meniscus measurement (OCT)
- Manual tear collection (tear composition)
- **Blink rate at t = 0, 45, 90 min [Fig. 3]**

Testing conditions:

- 5 normal patients, 5 DE patients
- Goggles worn for 90 minutes
- RH set to 23%

Potential confounding factors:

- Small sample size (n<30)
- Age variability amongst subjects
- Whether or not DE subject was on treatment plan at time of test

### CTGS Use Increases Eye Surface Irregularity

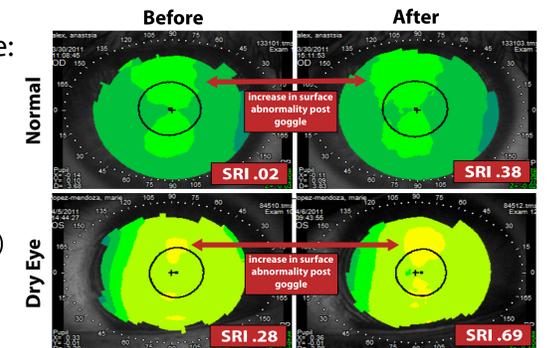


Figure 2. Surface Regularity Index (SRI) before & after CTGS use.

### CTGS Use Increases Blink Rate in DE Patients

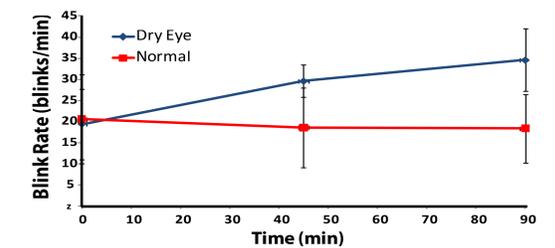
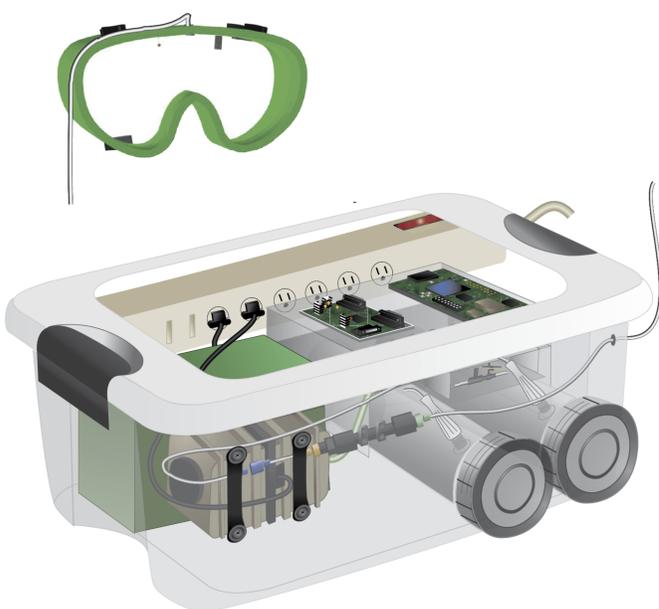
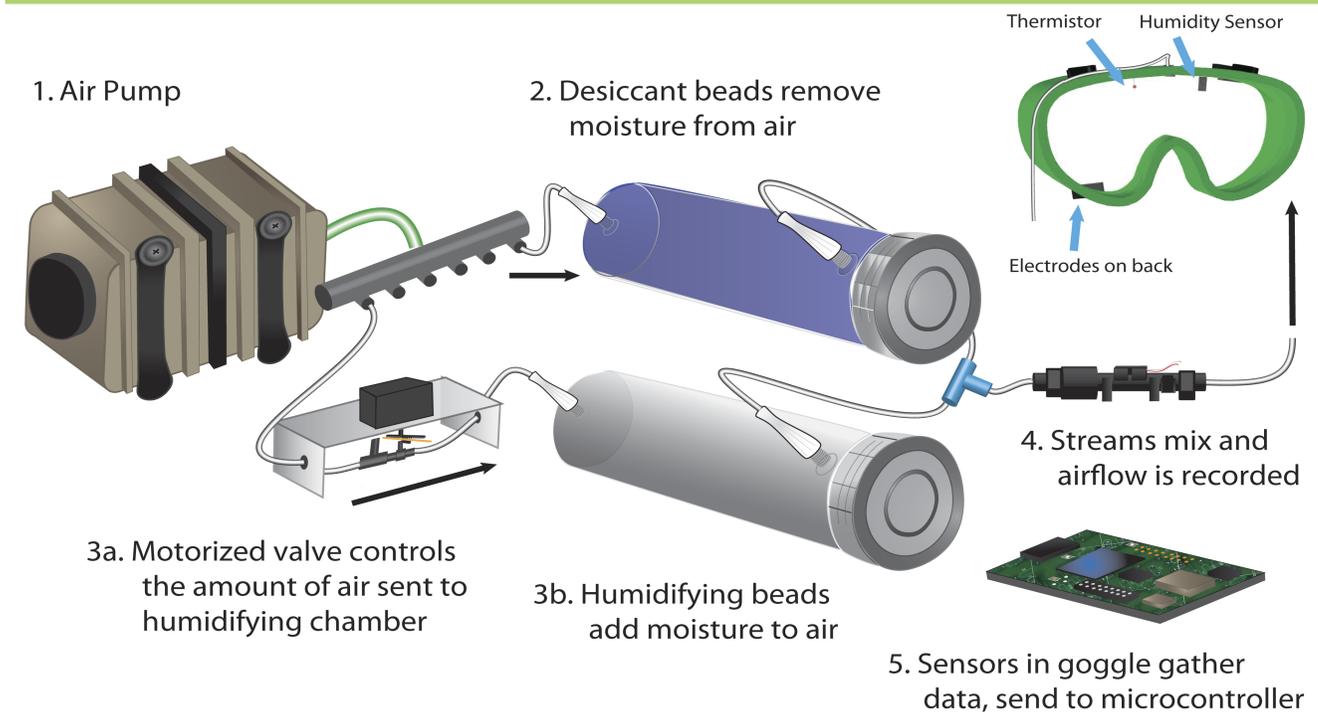


Figure 3. Blink rate in subjects over 90 min in CTGS

## Overall Design



## ClimaTears Goggle System (CTGS) Controls Relative Humidity



## Conclusions and Summary

The ClimaTears Goggle System enables:

- Standardization of testing conditions for both clinical and research applications
- Automatic recording of periocular temperature, relative humidity, airflow and blink rate
- Control of relative humidity between 15 and 40% ± 3%
- Manufacturing cost of <\$700 per device compared to >\$1 million for the leading competitor's product

**A clinical pilot study using the CTGS showed significant increases in DE symptoms, indicating potential use of the device as both a diagnostic and research tool.**

## References & Acknowledgements

1. "Definition and Classification of Dry Eye Disease: Report of the Definition and Classification Subcommittee of the International Dry Eye WorkShop (2007)." *The Ocular Surface* 5.2 (2007): 75-92. *The Ocular Surface: A Review Journal for Clinicians and Researchers*. 2007.
2. Dry Eye Disease (DED) Report. Rep. Custom Business Development & Management Technology, 25 Nov. 2009. Web. 19 Oct. 2010.

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