Cover Page of the Test Report

Report Number:RCS-2018-12

Sahnghai dermatology hospital

Health Related Product --- Testing Laboratory

Test Report

Project Acceptance Number	**CS-2018-12**
Name of Sample	**LED Mask**
Inspection Unit	**AdvantekOptoelectronics Technology (Changzhou) Co., Ltd**

YEAR 2018 MONTH 06 DAY 08

Report Number：RCS-2018-12

Sahnghai dermatology hospital
Health Related Product --- Testing Laboratory

Test Report

Project Acceptance Number： CS-2018-12 The First Page/ Total Five Page

Name and Number of Samples	LED Mask	Color and State	White (pearl lustre) / solid state
Inspection Unit	AdvantekOptoelectronics Technology (Changzhou) Co., Ltd	Production Date or Batch Number	2018/3/6
Production Unit	AdvantekOptoelectronics Technology (Changzhou)Co., Ltd	Quantity of Sample	35
Inspection Items	Evaluation of Anti-acne Cosmetics	Testing Reason	Evaluation of Clinical Efficacy of Removing Acne Production
Sample Date	2018-03-15	Inspection Completion Date	2018-05-4

一. Purpose of Test

The purpose of this test is to evaluate the acne repair effect of the LED mask apparatus after using it two weeks, as well as the safety during use of the product through clinical evaluation, instrumental testing, and subjects′ self-assessment.

二. Materials and Methods

1. Subject: A slight or moderate acne subject aged from 18 to 40, which need to be completed at least 30 cases. All subjects had read the informed consent report to understand the test process and volunteered to participate in the program.

Inclusion Criteria:

① Female volunteers with acne aged from 18 to 40;

② It accords with the diagnostic standard of normal acne and the I-II grading standard (Pillsbury includes grade 4 standard).

③ The use of topical anti-acne drugs was not continued within one month before the test, and systemic anti-acne drugs were not used within three months before the test.

④During the test, no other products of the same type were used except for the test samples; the use of drugs and other treatments related to acne (such as acne removal, and laser treatment) was stopped, and other products with acne repair effects were also prohibited;

⑤ During the test, it should be consent that no other products of the same type are used except for the test products;

⑥ Have read and signed the informed consent contract before the research.

Exclusion Criteria:

① Those who are under the age of 18 or over 40 are pregnant or lactating women.

② Sclerotic or Cystic acne, grade III-IV (severe) acne; occupational acne caused by chemicals, drug-induced acne;

③ Patients with severe heart, liver, kidney and hematopoietic disorders, as well as mental patients;

④ The use of antihistamines in the past week or the use of immunosuppressants in the past month; the use of any anti-inflammatory drugs in the test body site in the past three months;

⑤ Before the project test within three months, the new or changed oral contraceptives have been used, or contraceptives have been implanted;

⑥ Subjects with clinical inflammatory dermatosis; patients with asthma or other chronic respiratory diseases undergoing treatment;

⑦ Those who receive anti-cancer chemotherapy or insulin-dependent diabetes in the past 6 months; those patients who were with immunodeficiency or autoimmune diseases or those patients with high physical fitness; those who are not volunteers or who cannot complete the prescribed content according to the test requirements.

2.Test materials and method of use: Multi-source LED mask instrument, using blue light for irradiation during the test, each irradiation time is 20 minutes, the two irradiation time interval is over 48 hours, and the test period is used seven times in two weeks.

Test Methods

Subjects should not use any skin care products every time when testing their face. After reaching the test center, they should wash the face and sit for 30 minutes quietly. All tests were carried out in a laboratory controlled at a temperature of from 18° C to 22 ° C and a relative humidity is from 40-60%. Subjects should not leave the laboratory environment during the test.

Sahnghai dermatology hospital
Health Related Product --- Testing Laboratory
Test Report

All subjects should undergo clinical evaluation, self-assessment, and instrumental testing before using the products, after using three days later, one week later, and two weeks later.

3. 1 Clinical Evaluation

The dermatologist performs a acne count and safety assessment on the subject's face at each evaluation time. The acne count included inflammatory papules and non-inflammatory papule counts; The safety

assessment included erythema, edema, desquamation, and dryness. Evaluation criteria: 0 point means no, 1 point was divided into slight, 2 point was divided into moderate, 3 point was divided into severe.

3.2

Instrument Detection

3.2.1 Visia-CR

Visia-CR (Canfield Branch, USA) uses advanced optical imaging technology to obtain images from different sources of light by using white light, UV light, cross-polarized light, parallel polarized light, or a combination. Each subject simultaneously photographed facial images from three different direction with seven different light sources such as the front, left and right sides. Image J analysis software was used to measure the cumulative optical density of red fluorescence under the ultraviolet light source at different time points, and the effect of inhibiting the activity of Propionibacterium after using the LED mask was evaluated.

3.2.2

Imaging System with Laser Speckle Blood Perfusion

The laser speckle blood perfusion imaging system (Moor FLPI) detects the changes of superficial skin microcirculation blood flow in real time based on the principle of Doppler blood flow meter, and tests the results after 3 days, 1 week and 1 week later. After test, the subject should be evaluated the improvement of inflammation in the skin lesions after the product was used.

3.3 Self-evaluation

All subjects evaluated the efficacy, safety, and satisfaction of the product at different time points when the products were used. Among them, the efficacy evaluation indicators include the number and size of acne, the overall symptoms of acne and acne marks. The standard of scores is 1-3 point, namely grade three level. The lower the score, the better the acne repair effect. The safety evaluation includes dryness, burning, itching and thorn. The four indicators of pain should be used 5 grades level to assess, 1 point means completely disagree, 2 points means disagree, 3 points means no change, 4 points means agree, 5 points means completely agree, the lower the score, the better the safety is. And the percentage of the dominant results is statistically calculated, that is, the self-assessment result is under the 2 points.

4.Statistical Methods

All test results were statistically analyzed by using SPSS Stastistics 17.0. Measure data were used to calculate the mean and standard deviation. The measured values at different time points were compared with the baseline values using paired t test or paired rank sum test.

三、 Test Results

1.Subjects

A total of 32 subjects participated in the study, one person was lost to follow-up, and other 31 people completed all trials, with an age range of 19-39, and the average age is about from 24 to 34.

2.Clinical Evaluation

After using the LED mask, the number of inflammatory papules showed a downward trend. Compared with the baseline values, the number of inflammatory papules decreased significantly at different time points after using the mask (P<0.05). See the Table 1, Figure 1. There was no significant difference between the non-inflammatory papules and the baseline values (P>0.05).

After using two weeks of LED mask, the safety evaluation results of erythema, edema, desquamation and drying at different time points are shown in Table 2. There was no statistical difference between the time points and the basic values after using the productions(P>0.05).

Table 1 Results of Inflammatory and Non-inflammatory Papules at Different Time Points (Mean ± Standard Deviation)

	Base Value	3 Days	1 Week	2 Weeks
Inflammatory papule	11.5±7.0	10.3±6.8*	9.4±6.7*	8.9±6.2*
Non-inflammatory papules	3.1±5.3	2.9±4.5	4.8±5.8	3.2±3.3

Note: There is a statistical difference from the baseline values, * P < 0.05.

Sahnghai dermatology hospital
Health Related Product --- Testing Laboratory
Test Report

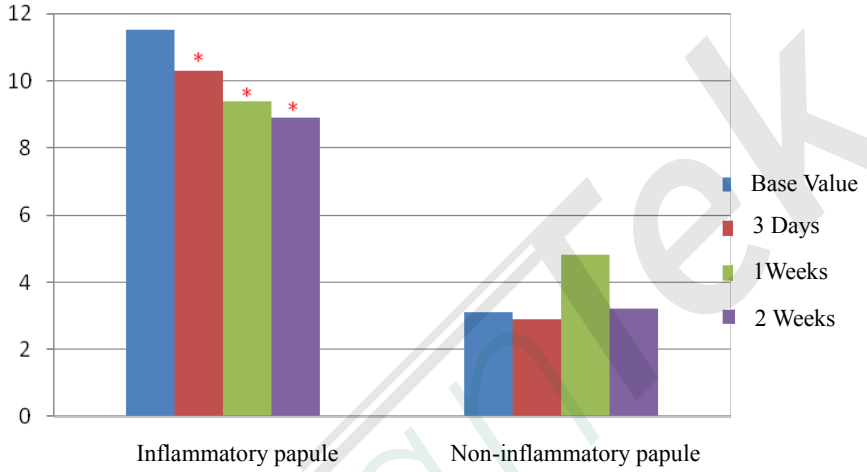


Figure 1 Clinical Evaluation Results at Different Time Points

Note: There is a statistical difference from the baseline values, * P < 0.05.

Table 2 Clinical Evaluation Results at Different Time Points (Sum (Minimum, Median, Maximum))

	Base Value	3 Days	1 Week	2 Weeks
Erythema	0 (0,0,0)	0 (0,0,0)	0 (0,0,0)	0 (0,0,0)
Edema	0 (0,0,0)	0 (0,0,0)	0 (0,0,0)	0 (0,0,0)
Desquamation	0 (0,0,0)	0 (0,0,0)	0 (0,0,0)	1 (0,0,1)
Dry	0 (0,0,0)	0 (0,0,0)	0 (0,0,0)	1 (0,0,1)

3.The Results of the Test

3.1Red Fluorescence Accumulated Optical Density

After using the LED mask, the cumulative red fluorescence density of the face at different time points was significantly lower than the base value, and there was a statistical difference (P<0.01), Findings in Table 3, Figure 2 and Annex 1.

Table 3 Red Fluorescence Cumulative Optical Density Detection Results at Different Time Points (Mean ± Standard Deviation)

Base Value	3 Days	1 Week	2 Weeks
11.5±7.0	318±325.5**	229.6±265.8**	240.5±321.1**

Note: There is a statistical difference from the baseline values, * P < 0.01.

Sahnghai dermatology hospital

Health Related Product --- Testing Laboratory

Test Report

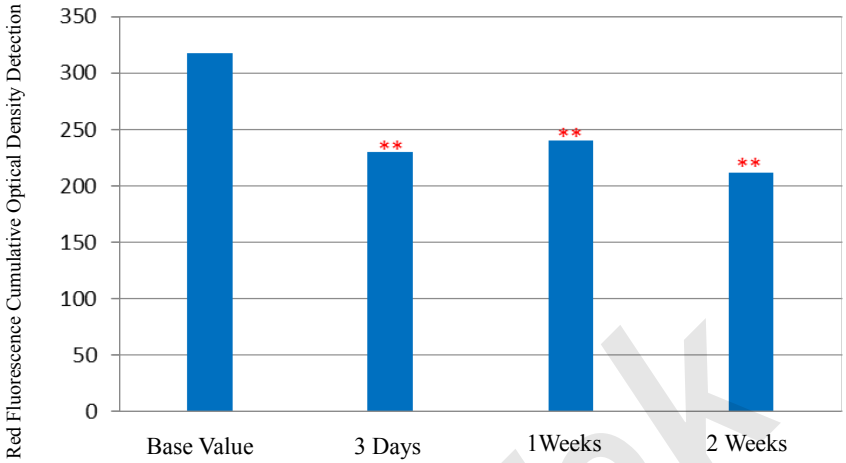


Figure 2 Red Fluorescence Cumulative Optical Density Detection at Different Time Points

Note: There is a statistical difference from the baseline values, * P < 0.01.

3.2Superficial Skin Blood Perfusion

After using the LED mask two weeks later, compared with the base value, the superficial skin blood perfusion decreased at the lesion site, and the difference was statistically significant (P<0.05). See Table 4, Figure 3 and Annex 2.

Table 4 Table 4 Results of Superficial Skin Blood Perfusion at Different Time Points (Mean ± Standard Deviation)

Base Value	3 Days	1 Week	2 Weeks
348.7±158.5	376.4±139.9	317.1±164.9	295.9±127.7*

Note: There is a statistical difference from the baseline values, * P < 0.05.

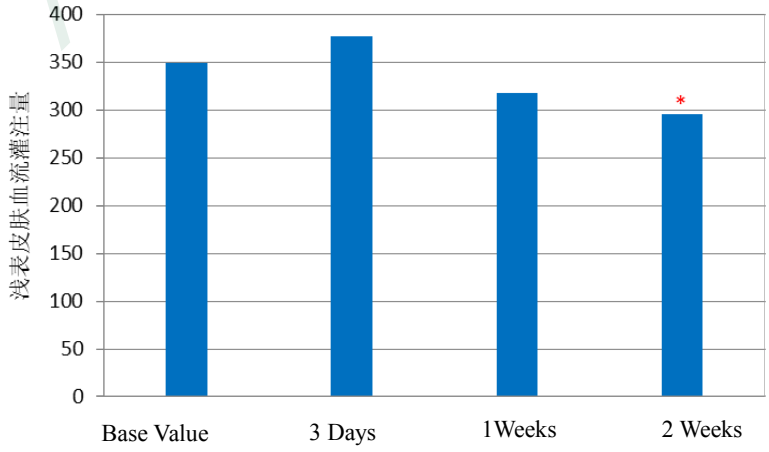


Figure 3 Superficial Skin Blood Perfusion at Different Time Points

Note: There is a statistical difference from the baseline values, * P < 0.05.

5.Self-evaluation

After using the product two weeks later, the subjects considered that the proportion of acne, size,

symptoms, and acne marks was gradually increased. The proportion of self-score is under 2 points in the above parameters was 77.4%, 87.1%, 80.6%, and 45.2%, respectively.

During the test, the number of cases of slight discomfort in self-assessment showed a downward trend. The specific evaluation results are shown in Table 5. It is believed that the proportion of products that are not led to dry, scorching, itchy and stinging is increasing, of which the score is under 2 points are 64.5%, 58.1%, 51.6% and 51.6%, respectively; At the end of the trial, the overall satisfaction of the subjects about productions was 96.8%.

Table 5 Self-assessment Results at Different Time Points (Number of Cases (%))

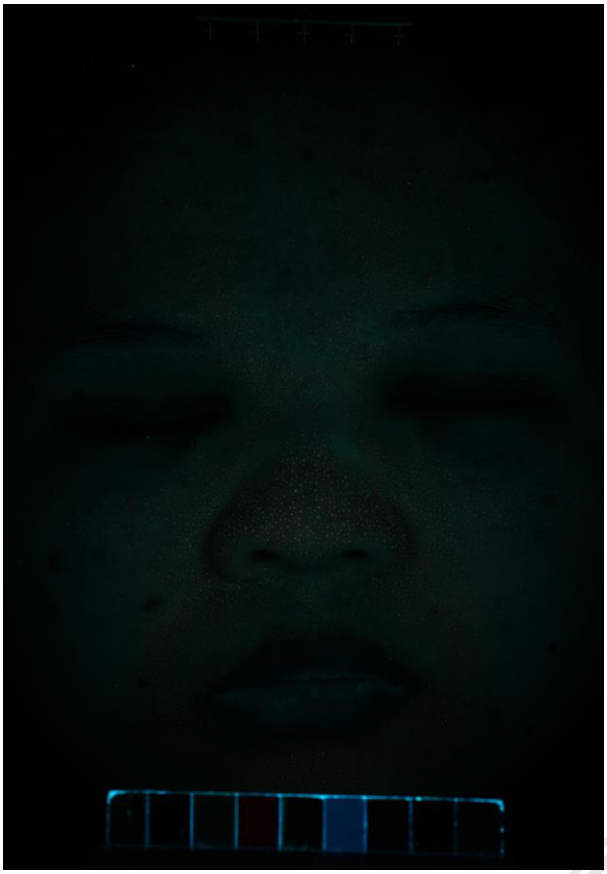
	3 Days	1 Week	2 Weeks
Number of acne	16 (51.6)	17 (54.8)	24 (77.4)
Size of acne	22 (71.0)	23 (74.2)	27 (87.1)
Symptoms of acne	19 (61.3)	22 (71.0)	25 (80.6)
Acne print	4 (12.9)	10 (32.3)	14 (45.2)
Dry	8 (25.8)	16 (51.6)	20 (64.5)
Searing	11 (35.5)	17 (54.8)	18 (58.1)
Itching	10 (32.3)	17 (54.8)	16 (51.6)
Stinging	10 (32.3)	16 (51.6)	16 (51.6)
Satisfaction	29 (93.5)	29 (93.5)	30 (96.8)

四、Conclusion

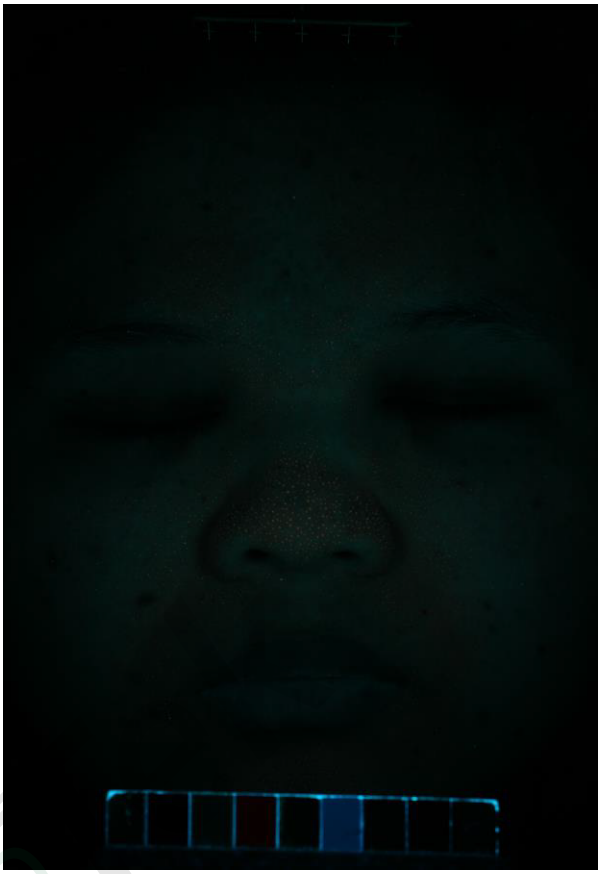
1. After using the LED masking two weeks later, the number of inflammatory papules, red fluorescen ce cumulative optical density and superficial skin blood perfusion were significantly lower than the bas eline value; 80.6% of the subjects thought that the symptoms of acne were significantly improved, 96. 8% of the subjects was satisfactory about the acne repair effect of the test product. Therefore, it can be considered that under the research conditions, the LED mask has a pretty acne repair effect.
2. In the course of this study, the clinical scores of erythema, edema, desquamation and dryness at each time point were not significantly statistics different from the baseline values.

Accessory 1

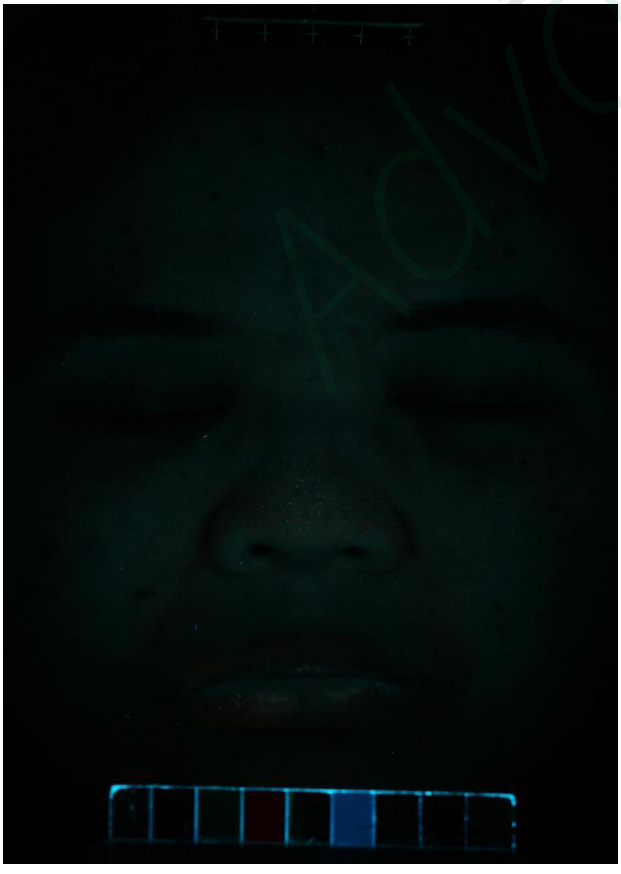
Visia Pictures at Different Times



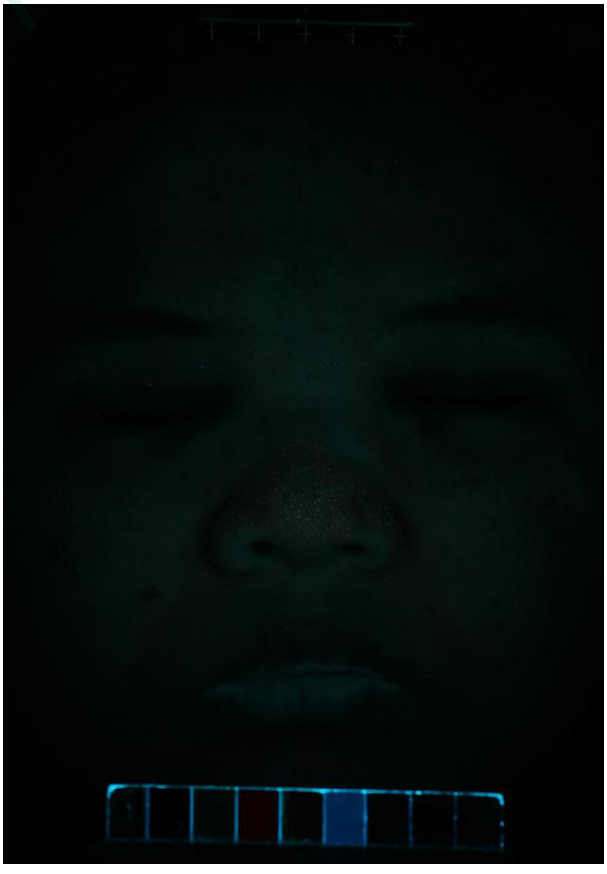
Base Value



Three Days



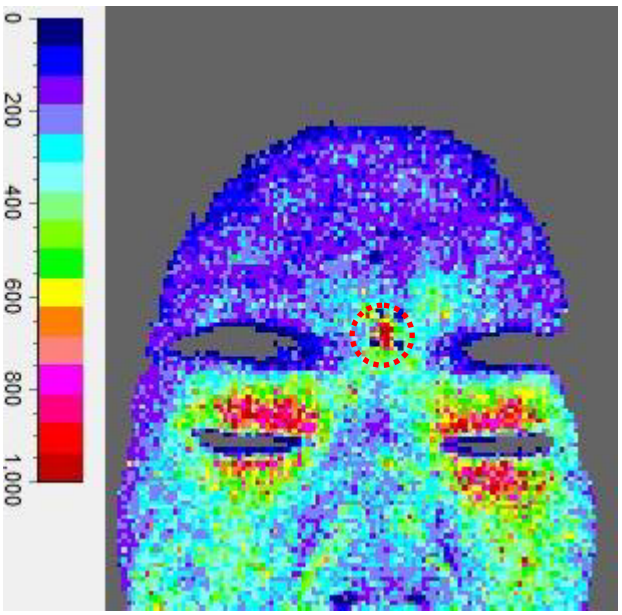
One Week



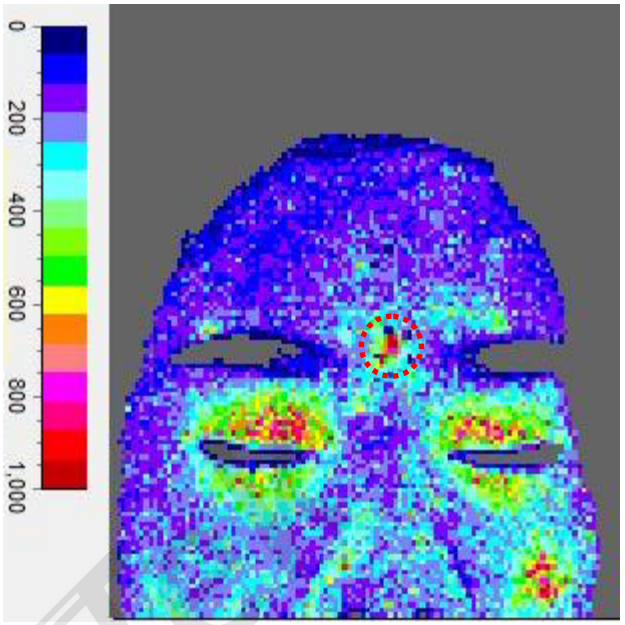
Two Week

Accessory 2

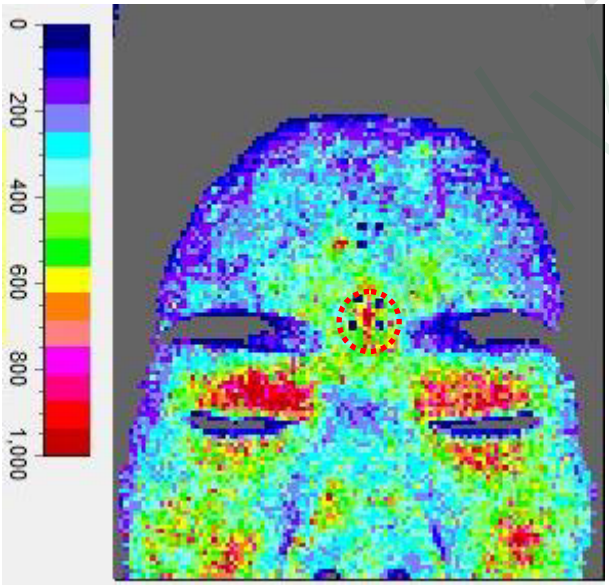
Pictures of Laser Speckle Blood Perfusion Imaging System at Different Times



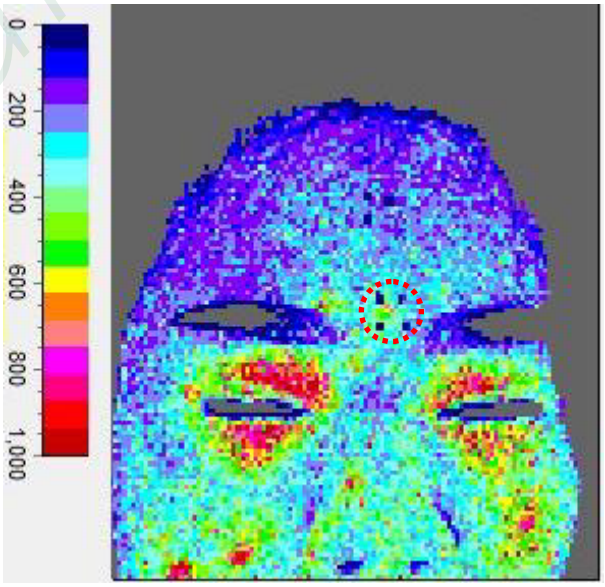
Base Value



Three Days



One Week



Two Week