MS-206B Home Use IPL Beauty Device Clinical test report

Product name: Home Use IPL Beauty Device

Model No.: MS-206B

Implementer: Clinical tab

Clinic Experiment Type: Clinical Trial

Made by: <u>Amanda</u> Audited by: <u>Ivan</u> Approved by: <u>Vicky</u>

Date:	10 th ,Sep.2017
Date:	17 th ,Sep.2017
Date:	21 th ,Sep.2017

I Clinical basic information(choice of disease, total case and illness case):

Subject: People needing hair removal, skin rejuvenation, acne treatment.

Topic: Clinical treatment effects of MS-206B for hair removal, skin rejuvenation, acne clearance.

Object: Verify the treatment effects and safety of this device by clinical experiments.

Target Areas: Skin rejuvenation on face and eyes area; hair removal on legs, arms, armpit, around lips etc area.

Total cases: 30

II Clinical Test Method

1. Make assessment: take photos and clean treated areas (need to shave hair before using the hair removal device; need to needle clearance on inflamed area before using the acne clearance) device disinfection.

2.Wear the protecting glasses before operation.

3. Device operation:

Hair removal:choose suitable energy level (from the lowest(level 1) to the highest(level 5), choose the optimum energy level according to treated person's feeling and max bearing capacity).

Let the light emitting window touched the treated site tightly and vertically, when the skin sensor indicators in the two sides of device bright, to press the emitting button for operation. (it's optimum when get warm feeling or see the reaction of hair follicle). In the first 3 treatments, do once in 1 week; in the 4-9 treatments, do once in 2-3 weeks. In the maintenance period, do one treatment every 2 months for area with hair regrowth.

Skin rejuvenation: choose suitable energy level (from the lowest (level 1) to the highest (level 5), choose the optimum energy level according to treated person's feeling and max bearing capacity). Let the light emitting window touched the treated site tightly and vertically, when the skin sensor indicators in the two sides of device bright, to press the emitting button for operation, and light spot on treated sites, along the skin texture, from bottom to upper, from inside to outside, operating for 3-4 times in that way (tiny warm feeling is ok, can operate more on worse part).

For rough skin, large pore or other skin problems, do one treatment in 1 week; for daily care, do one treatment in 1-2 weeks.

Acne clearance: choose suitable energy level (from the lowest (level 1) to the highest (level 5), choose the optimum energy level according to treated person's feeling and max bearing capacity). Let the ligh emitting window touched the treated site tightly and vertically, when the skin sensor indicators in the two sides of device bright, to press the emitting button for operation. After continuous operation on treated site, to check whether there are some reactions like scab, skin convergent etc and then decide if can operate again. For treated area, do one treatment in 2-3 days.

4. Clean treated area, make assessment, take photos, record related clinical data, treated person's feeling and skin eruption reaction etc.

5. Device disinfection.

III Clinical Assessment Standard:

Medical equipment registration standard

User manual of home IPL beauty device

IV Clinical Test Results:

Test Date Table:

Device type	Treatment Area	Treated person	Energy Level Level 1: the lowest	Interval (days)	Treatment Times	Treatment Result
			Level 5: the highest			
	Around lips	8	2、3	5 —8	5 —8 After treatments,hair	After treatments,hair growing
	Cheek near					period becomes longer; the
Hair removal	ears	6	2、3、4	14-30	5—7 14-30	new growing hair becomes thinner and less. It can reach the satisfied results after 7-9 treatments.
	Armpit	5	2、3、4、5		6 —9	
	legs	3	2、3、4		8 —9	
Skin rejuvenation	face	8	1、2、3、4	7 — 10	6 —10	You can find the results, like skin whitening, skin firming immediately after treatments. The flabby skin improved and became suppler, the wrinkles reduce or disappeared, and skin brightened with more treatments.
Acne clearance	face	10	2、3、4、5	2-3	8 — 10	Promote acne restored and healed,inflammation diminished, and prevent the acne marks formed with treatment.

Clinical pictures:

A. Hair removal results pictures:



Before treatment

After 3times treatment



Before treatment

The 15th day after 3 times treatment

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Before treatment

After 6 times treatment



Before treatment

After 7 times treatment





Before treatment

After 5 times treatment



Before treatment

After 2 times treatment

C、Acne clearance results pictures:



Before treatment

After 3 times treatment



Before treatment

After 5 times treatment



M Application scope、 contraindication and precautions:

Application scope, contraindication and precautions Application scope:

Suitable for people who need hair removal, skin rejuvenation or acne clearance.

Contraindication:

1. Pregnant and period time are forbidden;

2. Who has been bask in sun for a long time, should make skin restoration before the operation;

3. Who are sensitive to light are not allowed, can't be used with essential oil;

4.Who are suffering from heart disease, high blood pressure etc, burnt skin or hyperplasia are not allowed; 5.Not suitable for the teenage below 16 years old.

Precautions:

1.Need to wear the protecting glasses, don't look the light directly;

2. The tip should be touched skin tightly and vertically when operating;

3.Choose energy level from the lowest to the highest, depends on the max bearing capacity, the higher energy, the better results unless no harms to skin;

4.It's normal when the treated sites turn to tiny red or warm during operating, it can be cooled down by ice or cooling by itself;

5.Need to moisturizing and sun protection for skin after treatment.

IX Testing group

Clinical test personnel	Position	Job title	Department
Amanda	Clinical engineer		
Jane	Clinical engineer		