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EVALUATION OF THE EFFICACY OF A LIGHT PULSE PHOTO-DEPILATION PROCESS

Report (version 1):	**#09E0136 PH, February 09, 2011**
Price proposal:	**#09D0136-5**
Product:	**Adéna device**
Form and used:	**Hair pulse photo-depilation device** **Used on a body zone with white or blond hair**
Sponsor:	**EUROFEEDBACK** **3 rue de l'Aubrac** **ZI de la petite montagne sud** **91090 Lisses** **FRANCE**
Study monitor:	**Mrs Carole BAUMELOU**
Investigation site:	**Laboratoire DERMSCAN** Domaine scientifique de la Doua bâtiment CEI 2 56, boulevard Niels Bohr 69623 Villeurbanne Cedex - FRANCE
Study Managers:	**Mrs Claire JOSSAN / Cécile CHARMEL** **cjo@dermscan.com / cch@dermscan.com**

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Document: 1/1
(document including 37 pages)

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CERTIFICAT DE CONTROLE QUALITE

QUALITY INSPECTION STATEMENT

Numéro de l'étude clinique / *Clinical study number :*	09E0136 PH
Date de début de l'étude / *Study start date :*	July 27, 2009
Date de fin de l'étude / *Study completion date :*	January 14, 2010

L'étude référencée ci-dessus a été conduite conformément aux règles des Bonnes Pratiques Cliniques (BPC-ICH) et aux procédures opératoires standardisées de DERMSCAN.

The study listed above was conducted in conformance with Good Clinical Practice (GCP-ICH) and DERMSCAN standard operating procedures.

La personne habilitée à exercer le contrôle qualité final atteste du respect des règles et des procédures nommées ci-dessus.

The Quality inspection Auditor testifies to the respect of the rules, the standards and procedures listed above.

Nom / *Last name* :	BOUET
Prénom / *First name* :	Anne
Date / *Date* :	February, 10, 2011
Signature / *Signature* :	

E 06-F-024_V8

RESUME DU RAPPORT D'ETUDE N°09E0136

	Promoteur : EUROFEEDBACK **Adresse :** 3 rue de l'Aubrac ZI de la petite montagne sud 91090 Lisses FRANCE	**Investigateur : DERMSCAN** **Adresse :** Domaine scientifique de la Doua bâtiment CEI 2 56, boulevard Niels Bohr 69623 Villeurbanne Cedex - FRANCE

Titre de l'étude	**EVALUATION DE L'EFFICACITE D'UN PROCEDE DE PHOTO-DEPILATION PAR EMISSION DE FLASH LUMINEUX**		
Produit	**Référence :** Appareil Adéna	**Forme :** Photodépilateur	
Dates de l'étude	du 27 juillet 2009 au 14 janvier 2010		
Objectifs	- Evaluer l'évolution de la densité des poils blancs ou blonds, au cours de qutre séances d'utilisation du système. - Evaluer l'évolution de la densité des poils noirs ou châtains, - Evaluer l'appréciation subjective de son efficacité, de sa tolérance ainsi que de son "intérêt".		
Plan expérimental	- Etude en ouvert et en intra-individuel.		
Critères d'évaluation	Etude des variations de la densité des poils clairs (blancs ou blonds) et foncés (noirs ou châtains) par acquisition d'images au vidéomicroscope HIROX® et comptage à l'aide du logiciel Photoshop® CS3.	**Cinétique**	J0, J42, J84, J126, J168
		Méthodologie	Avant / Après
		Zone de mesure	Jambes ou torse
		Fréquence d'application	4 séances espacées de 42 jours
	Analyse des réponses données par les volontaires à un questionnaire d'évaluation subjective.	**Cinétique**	J168
		Méthodologie	Avant / après.
		Zone de mesure	Jambes ou torse
		Fréquence d'application	4 séances espacées de 42 jours
Population étudiée	Nombre de volontaires analysés : - Pour l'étude de la densité pilaire : 14 à J42, 14 à J84, 12 à J126 et 14 à J168. - Pour l'évaluation subjective : 14.		
	Age moyen : 50±5 ans (entre 23 et 76 ans).		
	Critères principaux d'inclusion : Sexe: féminin ou masculin Age: plus de 18 ans. Phototype : I à III. 8 sujets présentant des poils blonds et acceptant de se faire épiler une zone d'environ 15 cm² (5 cm X 3 cm) 8 sujets présentant des poils blancs et acceptant de se faire épiler une zone d'environ 15 cm² (5 cm X 3 cm)		
Résultats - Conclusion	**Dans les conditions expérimentales retenues, les séances de photo-dépilation ont :** - **présenté un effet significatif sur la repousse des poils se caractérisant par une diminution significative de la densité pilaire totale dès la première séance (-55% en moyenne).** **Après une séance, une diminution de 72% des poils foncés et de 41% des poils clairs (blonds ou blancs) a été observée.** **Plus précisément, sur les poils clairs, 27% des poils blonds et 51% des poils blancs ont disparus.** **Au cours des séances suivantes, les effets ont été maintenus sur les poils foncés et les poils blancs (respectivement -75% et -45% après quatre séances).** - **satisfait la majorité des volontaires pour son efficacité. 71% des volontaires ont estimé que la technique utilisée était efficace et 61% ont attribué une note ≥5 sur une échelle d'efficacité de 0 à 10.** **57% des volontaires ont constaté qu'après quatre séances, peu à pas de poils traités avaient repoussé.** **D'un point de vue confort, 43% des volontaires n'ont pas ressenti de sensations désagréables lors des séances de photo-dépilation et 70% ont attribué une note <2 sur une échelle de douleur de 0 à 10. 50% des volontaires seraient prêt à utiliser cette technique sur une zone plus grande.**		

Cécile CHARMEL **Assistante Responsable d'Essais**	**Date** 11 février 2011	**Signature**

SUMMARY OF THE STUDY REPORT # 09E0136

	Sponsor: EUROFEEDBACK **Address:** 3 rue de l'Aubrac ZI de la petite montagne sud 91090 Lisses FRANCE	**Investigator: DERMSCAN** **Address:** Domaine scientifique de la Doua bâtiment CEI 2 56, boulevard Niels Bohr 69623 Villeurbanne Cedex - FRANCE
Study Title	**EVALUATION OF THE EFFICACY OF A LIGHT PULSE PHOTO-DEPILATION PROCESS**	
Product(s)	**Reference:** Adéna device	**Form:** Hair pulse photo-depilation device
Study date(s)	From July 27, 2009 to January 14, 2010.	
Objective(s)	- Evaluation of the evolution of the light hair density (white and blond) during four sessions of device use, - Evaluation of the evolution of the dark hair density (black and brown), - Evaluation of the subjective appreciation of its efficacy, its tolerance and its benefit.	
Experimental plan	- Open and intra-individual study.	

Assessment criteria			
	Study of the variations of the light hair (white and blond) and dark hair (black and brown) density by images acquisition with videomicroscope Hirox® and analysis using Photoshop CS3® software.	**Kinetics**	D0, D42, D84, D126 and D168
		Methodology	Before / After
		Measurement zone	Legs or thorax
		Application frequency	4 sessions spaced of 42 days
	Subjective evaluation (questionnaire).	**Kinetics**	D168
		Methodology	Before / After
		Measurement zone	Legs or thorax
		Application frequency	4 sessions spaced of 42 days

Studied population	Number of subjects analyzed: - for the study of the hair density: 14 on D42, 14 on D84, 12 on D126 and 14 on D168. - for subjective evaluation: 14.
	Average age: 50±5 years (between 23 and 76).
	Main inclusion criteria: Sexe: female or male Age: 18 years old and more. Phototype : I to III. 8 subjects with blond hair agreeing to have a shaved zone of 15 cm² (5 cm X 3 cm) 8 subjects with white hair agreeing to have a shaved zone of 15 cm² (5 cm X 3 cm)
Results - Conclusion	**Under these study conditions, the photo-depilation sessions induced:** - **a significant effect on hair growth characterized by a significant decrease in the total hair density from the first session (-55% on average).** **After one session, a decrease in 72% of dark hair and 41% of clear hair (white or blond) was observed.** **More precisely, on clear hair, 27% of blond hair and 51% of white hair disappeared.** **During the following sessions, the effects were maintained on dark and white hair (respectively -75% and -45% after four sessions).** - **a satisfaction of the majority of the subjects for its efficacy. 71% of the subjects have esteemed that the technical was efficient and 61% have attributed a note ≥5 on an efficacy scale range from 0 to 10.** **57% of the subjects have noticed that after four sessions, few or none hair hava grown.** **Regarding confort, 43% of the subjects did not felt any unpleasant sensation during the photo-depilation sessions and 70% have attributed a note <2 on a pain scale range from 0 to 10. 50% of the subjects would continue this technical on a largest zone.**

Cécile CHARMEL **Trial Manager Assistant**	**Date** February 14, 2011	**Signature**

Laboratoire Dermscan

1. AIMS

1.1. Primary objective

The primary objective of this study was to analyse, the evolution of the density of white and blond hair during four sessions of photo-depilation with Adéna device (D0, D42, D84 and D126).

1.2. Secondary objectives

The secondary objectives of this study were to evaluate, for the studied device:

- the evolution of the density of black hair on the studied zone (for the subjects with some),
- the subjective appreciation of its efficacy, its tolerance and its benefit.

2. METHODS

2.1. Trial period

Material reception:	July 10, 2009
Beginning of the study:	July 27, 2009
End of the study:	January 14, 2010
First results by e-mail:	September 18, October 30, December 11, 2009, January 29, 2010 and August 26, 2010.

2.2. Experimental plan

This was an open, intra-individual study; each subject was his/her own control.

2.3. Assessment criteria

2.3.1. Primary criterion

- Study of the density variation of light hair (white and blond) by images acquisition with videomicroscope Hirox® and analysis using Photoshop CS3® software.

2.3.2. Secondary criteria

- Study of the density variation of dark hair (black and brown) by images acquisition with videomicroscope Hirox® and analysis using Photoshop CS3® software,
- Analysis of the subjects' answers to a subjective evaluation questionnaire.

2.3.3. Principles

2.3.3.1. Images acquisition with videomicroscope

The studied zone was visualized with videomicroscope HIROX®. It's a mobile, fiber optic x20 lens, coupled with an image acquisition computer system.

The used lens putted directly in front of the studied zone without contact, allows to visualize a 14 cm² zone.

2.3.3.2. Analysis of the hair density with Photoshop CS3® software

On each image realised (before and after coloration), the hair have been counted using Photoshop CS3® software.

Example of counting on uncoloured hair (dark hair visualization (black or brown hair)).

Example of counting on coloured hair (dark and light hair visualization (black or brown hair and white or blond hair)).

The difference between counting after and before colouring allows to count the light hair (white or blond hair).

2.3.3.3. Subjective evaluation questionnaire

A subjective evaluation questionnaire, prepared by the clinical trial center and submitted to the sponsor, was filled in by the subjects at the end of the study to subjectively evaluate the characteristics of the studied device, its global efficacy and its future use.

2.4. Methods pertinence

2.4.1. Hair density

The videomicroscope allows the acquisition of images at the different times of the kinetic before and after device use. The analysis of these images with Photoshop CS3® software gives a quantitative evaluation of the device efficacy on hair density.

2.4.2. Subjective evaluation questionnaire

Answers given by the subjects to a subjective evaluation questionnaire allow to evaluate the characteristics, the efficacy and the security of the studied device. These subjective criteria give, in particular, accurate information regarding product appreciation.

2.5. Subject selection

2.5.1. Number of subjects

The study was done on a minimum of 16 subjects, at sponsor's request.

2.5.2. Inclusion criteria

General criteria
Healthy subject.
Subject having given his/her informed, written consent.
Cooperative subject, aware of the necessity and duration of controls so that perfect adhesion to the protocol established by the clinical trial center could have been expected.
Specific criteria
Sexe: female or male
Age: 18 years old and more.
Phototype : I to III.
8 subjects with blond hair agreeing to have a shaved zone of 15 cm^2 (5 cm X 3 cm).
8 subjects with white hair agreeing to have a shaved zone of 15 cm^2 (5 cm X 3 cm).

2.5.3. Non-inclusion criteria

Pregnant or nursing woman or woman planning to get pregnant during the study.
Cutaneous pathology on the studied zone (melanoma, herpes, psoriasis, cutaneous tumour, eczema, scar,..etc).
Use of topical or systemic treatment during the previous weeks liable to interfere with the assessment of the material's security.
Exposure to sunlight or UV-rays the previous month the beginning of the study
Subject enrolled in another clinical trial during the study period.
Epileptic subjects ((related to the luminous flashes).
Taking of photo sensitizing product seven days before the sessions (tanning product, activator, tanning shower, essential oils, etc…).
Subject with a pacemaker.

2.5.4. Compliance assessment

If the protocol was not respected and if the deviation was minor, the technician or the investigator warned the subject of the importance of respecting the prescribed protocol. If the subject persisted or if the deviation was major, the subject was declared non-compliant. In this case, the subject was removed from the study for non-compliance.

The uses of the device were done by the technician in charge of the study in the laboratory.

2.5.5. Restrictions during the study

Only the usual cleansing and care products were authorized on the studied zone during the study.

No exposure to sunlight or UV-rays during the study was authorized.

2.6. Operational aspect

2.6.1. Trial schedule

On W-1

- Subjects came to the laboratory without having applied any product to the body since the previous evening.
- They read, signed and dated the information sheet (instructions on the product use and restrictions related to the study) and informed consent forms in duplicate. These documents were also signed and dated by the person who conducted the informed consent discussion. The subjects received a copy.
- Verification of inclusion and non-inclusion criteria.
- Definition of the studied zone according to the subject hairiness and shaving of a zone near this one.
- Realization of the device test following the protocol describes in paragraph 2.7.7 on a shaved zone near to the studied zone (intensity according to the phototype). Then checking of the lack of reaction 10 minutes after the test.
- The volunteers received as consigns not to expose them to the sun in the two weeks following the sessions.

On D0

- Subjects came to the laboratory without having applied any product to the studied zone since the previous evening.
- Shaving of the studied zone on S-1 (15 cm^2 zone, 50 mm X 30 mm) in order to reduce the length of the hair.
- Image acquisition of the studied zone before coloration (for the visualization of the dark hair).
- Coloration of the hair of the studied zone.
- Image acquisition of the studied zone after coloration (for the visualization of the light hair).
- Hair removal of the 15 cm^2 zone with hot wax.
- Use of the studied device according to the protocol describes in paragraph 2.7.7.
- Collection of the possible unpleasant feelings.

On D42, D84, D126 and D168

- Subjects came to the laboratory without having applied any product to the studied zone since the previous evening.
- Shaving of the studied zone on S-1 (15 cm² zone, 50 mm X 30 mm) in order to reduce the length of the hair.
- Image acquisition of the studied zone before coloration (for the visualization of the dark hair).
- Coloration of the hair of the studied zone.
- Image acquisition of the studied zone after coloration (for the visualization of the light hair).
- Hair removal of the 15 cm² zone with hot wax (except on D168).
- Use of the studied device according to the protocol describes in paragraph 2.7.7 (except on D168).
- Collection of the possible unpleasant feelings (except on D168).
- Subjects answered to a subjective evaluation questionnaire (only on D168).

2.6.2. Adverse Events/Serious Adverse Events

During the study, the following rules were applied:

2.6.2.1. Definitions

An Adverse Event (AE) is defined as any noxious symptom, temporarily linked to the use of a study product, occurring in a subject taking part in a clinical trial, whether or not this symptom is related to the studied product(s).

An adverse reaction is defined as any noxious and unexpected reaction that might be related to the studied product(s).
All adverse events judged, by the investigator, as being possibly, probably or certainly related to the studied product are considered as adverse reactions.

A Serious Adverse Event (SAE) is defined as an adverse event or effect that:
- results in death (note: death is the outcome, not the event),
- is life threatening,
- requires in-patient hospitalization (at least one night) or prolongation of existing hospitalization (does not include hospitalization scheduled before the inclusion),
- results in persistent or significant disability or incapacity,
- is a congenital anomaly/birth defect,
- is considered like by the investigator.

The severity/intensity of adverse events can be graded on a three-point scale:
- Mild or *Grade 1*: discomfort noted, but does not disturb normal daily activities.
- Moderate or *Grade 2*: discomfort sufficient to reduce or affect normal daily activities.
- Severe or *Grade 3*: inability to work or have normal daily activities.

2.6.2.2. Documentation

All concomitant treatments are reported in the CRF and the study report.
All Adverse Events likely to be related to the studied product (adverse reactions) are reported in the CRF and the study report.
All Serious Adverse Events are reported in the CRF and the study report.

2.6.2.3. Notification

The investigator declares to the sponsor, by fax or e-mail, the occurrence of adverse reactions according to their severity and their unexpectedness (according to the investigator's advice).

All Serious Adverse Events are transmitted by e-mail to the sponsor without delay, at the latest 24 hours after knowledge of their occurrence.
A SAE declaration form signed by a physician is sent, within 48 hours, by fax or e-mail with acknowledgement of receipt.

2.6.2.4. Follow-up

When an adverse event likely to be linked to the studied product or the protocol persists at the end of the study, the Investigator ensures that the subject is followed up until total resolution of the event or stabilization of the symptoms without taking off the application of the obligations and the responsibilities of the sponsor.

2.6.2.5. Occurrence of pregnancy

The occurrence of a pregnancy (reported or diagnosed) after inclusion in the study is considered as an intercurrent event not related to the studied product(s) nor the protocol and induces the immediate dropping out of the subject.
A follow-up will be done according to the current internal procedures up to the end of the pregnancy or to its interruption.

2.6.2.6. Premature termination of the study

♦ **Study exit conditions**

* In compliance with the Helsinki Declaration (1964) and its successive updates and with the French law 2004-806 dated August 9, 2004 concerning public health (ref: 1 to 3 in §8.1), subjects have the right to exit from the study at any time and for any motive.

* The investigator can also interrupt the subject participation in the study prematurely in the case of a disease occurrence, a pregnancy or the occurrence of an adverse reaction.

* The sponsor can demand that any subject be excluded from the study for major infringements to the protocol, for administrative reasons or any other motive.

Nevertheless, premature removal of a high percentage of subjects from the study can make the study difficult or impossible to interpret. Consequently, any premature exit without valid motives should be avoided as much as possible and is carefully documented in the case report form, the final report and, if necessary, in the Adverse Event form.

Every premature exit must be classified under one of the following headings:
- presence of a non-inclusion criteria,
- Adverse Event occurrence,
- Serious Adverse Event occurrence,
- withdrawal of consent,
- untraceable panelist,
- appearance of non-inclusion criteria,
- non-adherence to the protocol,
- other reason.

♦ **Replacement conditions**

No replacement was foreseen as 10% additional subjects were planned to be included in the study.

2.6.3. Collection and validation of data

According to the law "informatique et libertés" (ref: 4 in §8.1), an identification code was attributed to each subject on purpose to keep his identity confidential. This code consists of: the first three letters of the subject's name and the first two letters of his first name.

The personnel in charge of the study (technician, physician,...) added data to subject case report form and to a computerized data base.
Data were validated by Dermscan's study manager.

2.6.4. Audit and trial monitoring visit

An audit and/or trial monitoring visit might be carried out at the sponsor's request or by the appropriate regulatory authority. The aim of the monitoring visit is to verify that the study is conducted according to the determined protocol and current regulations.

2.6.5. Quality assurance and quality control

In order to ensure the conformity of the clinical trials to the study sponsor's requirement, DERMSCAN has implemented a quality management system which has been certified ISO 9001: 2008 by AFNOR certification.
This quality assurance system includes Good Clinical Practices (GCP) and regulation requirements.

Each study report is the subject of a quality inspection by a member of the DERMSCAN Proofreading Committee. The proofreader is chosen because he(she) is not involved in the audited study. The inspection of the study report allows to confirm that the results reflect exactly the study raw data.

A certificate of quality inspection, signed by the person who checked the report is enclosed in each study report to certify that the study report reflects the study raw data and fulfils any standard and regulatory requirements.

2.7. Studied device

2.7.1. Confidentiality procedure

The studied device has been supplied by the sponsor in its commercial form.

2.7.2. Storage

Before the beginning of the study, the device and the associated products were kept at room temperature in a dedicated air-conditioned room. This room is locked and access controlled.

The translucent gel was kept kept at +4°C in a fridge in a dedicated air-conditioned room. This room is locked and access controlled.

2.7.3. References

For the photo-depilation:

1- Adéna device,
2- Gel pour échographie Premium,
3- Lingettes démaquillante visage et yeux,
4- BiafineAct®,
5- Nexcare coldhot pack,
6- Glasses,
7- White pencil Sephora®.

For the hair removal :

8- Wax Warmer Dépilève®,
9- Bande d'épilation non tissées Ylas®,
10- Cire Dépilève®,
11- oil cleanser Depilève®,
12- Facial Applicator Spatulas.

2.7.4. Aspects

1- Light pulse photo-depilation device,
2- Translucent gel,
3- White lingette,
4- White emulsion,
5- Blue gel,
6- Black glasses,
7- White pencil,
8- Electrical device,
9- Pink paste,
10- Blue gel,
11- Blue liquid,
12- Wooden spatula.

2.7.5. Labeling

Example of labeling of each product by the clinical trial center and translation:

DERMSCAN Etude n°	DERMSCAN Study #
N° vol : non applicable En cas d'urgence : n° tél…… N°Dermscan : …….. Conservation : …… A tenir hors de portée et de la vue des enfants. A utiliser sous stricte surveillance médicale pour essai clinique.	Subject#:not applicable. Emergency telephone number: …….. Dermscan ref.:…… Conservation: …….. Keep out of reach and sight of children. To be used only under strict medical supervision for clinical trial.

2.7.6. Application frequency

Four sessions of photo-depilation were realised: one each 42 days (D0, D42, D84 and D126).

2.7.7. Application site and method

Site :

Legs or thorax according to the subjects.

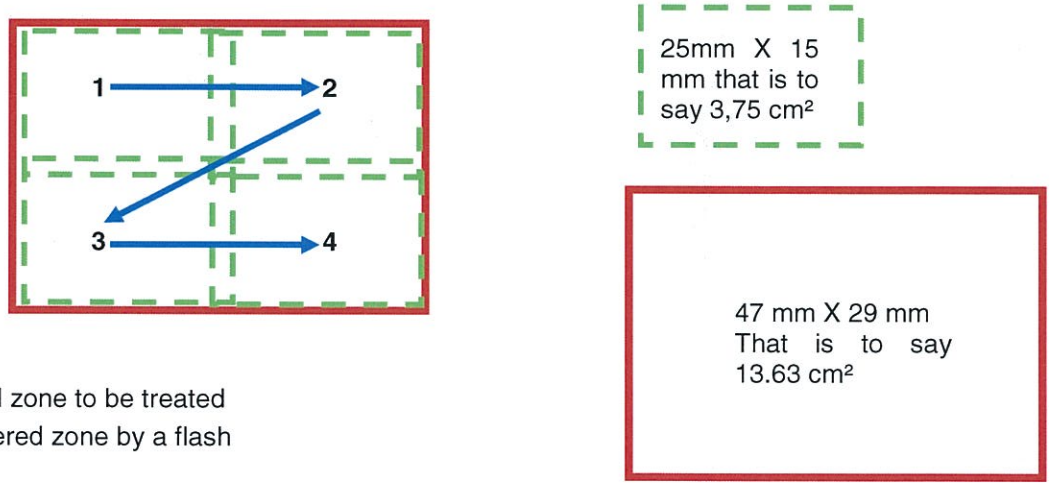
Method:

The use of the device was done on an epilated skin with hot wax (or shaved for the test),
- cleanse the optical cable and the studied zone.
- 3 minutes after hair removal, cool down the zone with an ice cube until the temperature at the surface of the skin be at 5°C maximum.
- The subject and the technician put safety glasses.,
- Spead out 2 mm of translucent gel at 5°C on the studied zone.
- Check the cleanliness the applicator (yellow filter)
- Press the optical conduit on the skin.
- Start the flash by pushbutton.
- move the conduit on the studied zone by respecting an overlapping of 2mm between two flashes.
- Continue the treatment all over the zone.

The surface of the sensor was: 3.75 cm ²: 25 mm X 15 mm.
The surface of the treated zone was: 13 cm ²: 47mm X 29mm.

The number of flash realized on the zone had to be of four in order to treat the whole zone.

Follow the following illustration:



- At the end of the treatment, press the pause button
- cleanse the optical conduit
- cool down the treated zone with an ice pocket during 2 minutes,
- Apply a soothing cream "BiafineAct®"on the studied zone.

2.7.8. Device issue

Not applicable, the sessions of photo-depilation were realized at the laboratory by the technician in charge of the study.

2.7.9. Device future

The device and the unused products were sent back to the sponsor at the end of the study.

2.8. Method of attribution to the subjects

2.8.1. Randomization method for the application zones

Not applicable. There was no randomization, the choice of the zone was done according to the hairiness of the subjects.

2.8.2. Attribution

Not applicable. All the subjects tested the same device.

2.9. Data analysis

2.9.1. Calculation formulas

The raw variations (Δ) and in percentage (Δ%) of the different studied parameters were calculated according to the following formulas:

$$\Delta = (TZ_{ti} - TZ_{t0})$$

$$\Delta\% = \frac{(TZ_{ti} - TZt0)}{TZ_{t0}} \times 100$$

with:
TZ: value obtained on the treated zone,
t0: before application,
ti: at each measurement time after application.

Remarks:

The percentage of the variation (Δ%) is expressed in percentage of the variation on the measurement's zone (TZ_{ti} - TZ_{t0}). These variations are balanced at the initial value TZ_{t0} (before application).

This expression (Δ%), therefore, gives the variation, in percentage, on the measurement's zone compared to the initial conditions (TZ_{t0}).

Measured values are presented in raw value tables. These tables also show the descriptive statistics: means, medians, minima, maxima, standard errors of the means (SEM) and confidence intervals of 95% (95% CI).

Also, raw variations, percentage variations, descriptive statistics and the results of the statistical analysis (p) are presented in the variation tables.

2.9.2. Statistical method

The statistical analysis determined the significance of the measurement variations obtained under the effect of the tested product.

The comparison was on the values obtained before and at the different times of kinetics after treatment.

Data were analyzed with a **paired t-test**. This method tests whether the mean of sample differences between pairs of data is significantly different from the hypothetical mean, zero under the null hypothesis (H0).

The alternative hypothesis (H1) was that the average difference was either greater or less than 0 (two-tailed test). Before carrying out a test, a type I error of 5% was chosen (which corresponds to the risk of rejecting a true null hypothesis).

→ **If $p \leq 0.05$**, H0 was rejected. There was a significant difference between before and after the treatment.

→ **If $p > 0.05$**, H0 was accepted, the mean was not different from 0. Data did not show a significant difference between before and after the treatment.

2.9.3. Statistical software

The software used was EXCEL version 2003.

2.10. Archives

Data will be securely archived digitally and on paper for ten years from the date of dispatch of the final report. At the end of this period, the study archives will be destroyed unless otherwise stipulated in writing by the sponsor.

All the documents relating to this study are archived during one year maximum at Dermscan before being sent to the company LOCARCHIVES (Parc industriel de la plaine de l'Ain – Allée des cèdres – 01150 SAINT-VULBAS – FRANCE).

3. STUDY FOLLOW-UP

3.1. Population

	Number of subjects			Reason(s)	
	Included subjects	Subjects who completed the study	Analyzed subjects	Subjects who did not complete the study	Non-analyzed subjects
D42	*16*	*16*	*14*	/	**
D84		*15*	*14*	**	**
D126		*14*	*12*	**	*Subject #8: problem with the image acquisition after coloration of the studied zone making impossible the analysis of this data. Subject #2 : following a problem with image acquisition these subject's data were not analysed.*
D168		*14*	*14*	**	/

**:
Subject #16: dropped out because of an adverse event occurred at D46 (burn on the studied area because of the study protocol, make the following photo-depilation session impossible).
This subject wasn't analyzed.
Subject #6: dropped out at D126 because of an adverse event occurred after D42 session (burn on the studied areabecause of the study protocole, make the following photo-depilation session impossible).
This subject wasn't analyzed.

3.2. Protocol non-adherences

No protocol non-adherence was observed during the study.

3.3. Audit / Trial monitoring visit

Visit of Mrs. BAUMELOU and Mr. SAFRAOUI on July 16, 2009 for the study monitoring.
Visit of Mr. DOS SANTOS on February 5, 2010 for a review the results of the study.
Visit of Mrs. BAUMELOU and Mr. SAFRAOUI on February 5, 2010 for a new review the results of the study.

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4. SUBJECT CHARACTERISTICS

The table below presents the observations concerning the subjects included in the study.

Subject	Last name	First name	Age	Sex	Hair color	Hairs color	Phototype	Medical events or treatments occurred during the study	Comments	Inclusion date	End date
1	DIN	CA	24	F	B	Blond	I	Amoxicilline from August 02 to 09, 2009, Ibuprofene on September 02, 2009, Hextril® from August 02 to September 07, 2009, Ibuprofene on November 30, 2009	none	July 27, 2009	January 12, 2010
2	BEA	MA	60	F	B	Blond	I	Biprofenid® on August 01 and November 20, 2009, Doliprane® on August 15 and September 03, 2009	none	July 27, 2009	January 12, 2010
3	AMA	CH	58	M	B	White	II	none	none	July 27, 2009	January 12, 2010
4	BAS	CL	63	M	DB	White	II	none	none	July 27, 2009	January 12, 2010
5	COL	AN	65	M	W	White	I	Diprosone® from July 30 to August 07, 2009 (erythema because of depilation)	none	July 27, 2009	January 13, 2010
(6)*	(GEI)*	(JE)*	(24)*	(F)*	(Bc)*	(Blond)*	(III)*	(Burn after D42 and depigmentation on the zone still present on D126)*	(Dropped out on D126)*	July 27, 2009	December 02, 2009
7	BUR	NA	35	F	G	Blond	I	none	none	July 27, 2009	January 13, 2010
8	GUI	RO	64	M	DB	White	I	none	D90 instead of D84 : pimple on the zone.	July 27, 2009	January 14, 2010
9	LAY	GE	59	M	W	White	I	Polery® since January 08, 2010 (caugh)	none	July 27, 2009	January 14, 2010
10	CHA	LA	29	F	B	Blond	II	Lisopaïne® on September 22 to 25, 2009, Paracétamol® from November 23 to 24, 2009.	none	July 27, 2009	January 13, 2010
11	CHA	MA	23	F	B	Blond	III	Ibuprofene 400 mg on August 11, 2009, (Ibuprofene on September 13 and 14, 2009.	Appearance of brown spot after the first photodepilation from July 30, 2009 to August 12, 2009 (disappearance after a scrub)	July 27, 2009	January 13, 2010
12	RIV	AL	59	M	W	White	II	Rhinureflex® and Hélicidine® from October 2 to 6, 2009, jab against flu on October 02, 2009, Diclofenac® RPG 50mg and Lamaline® from november 24 to December 01, 2009.	none	July 27, 2009	January 12, 2010
13	COR	JE	57	M	BC	Blond	II	none	none	July 27, 2009	January 14, 2010
14	DUF	CO	30	F	DB	Blond	I	none	none	July 27, 2009	January 14, 2010
15	TRU	GU	76	M	W	White	I	none	none	July 27, 2009	January 14, 2010
(16)*	(DAR)*	(GE)*	(63)*	(M)*	BC	(White)*	(III)*	(Second-degree burn on September 10, 2009)*	(Dropped out on D46)*	July 27, 2009	September 14, 2009

Mean	50	**F**	6	**W**	4	**Blond**	7	**I**	8
Median	59	**M**	8	**B**	5	**White**	7	**II**	5
Minimum	23			**BC**	2			**III**	1
Maximum	76			**DB**	3			**IV**	0
SEM	5			**D**	0			**V**	0
95% CI	10			**G**	1			**VI**	0

Legend: DO: subject dropped out during the study
()*: values not included in data analysis

F: female
M: male

N: normal skin
D: dry skin
C: combination skin
G: greasy skin

W: White
B : Blond
BC : Brown clear
DB : Dark brown
D: Dark
G: Ginger

5. RESULTS

5.1. Hair density

Tables of individual results are presented in **Appendices 9.1 to 9.3**.

The studied parameter is the density of black, brown, blond and white hair (nb/cm²).
A decrease of the hair density characterizes the efficacy of the photo-depilation on hair growth.

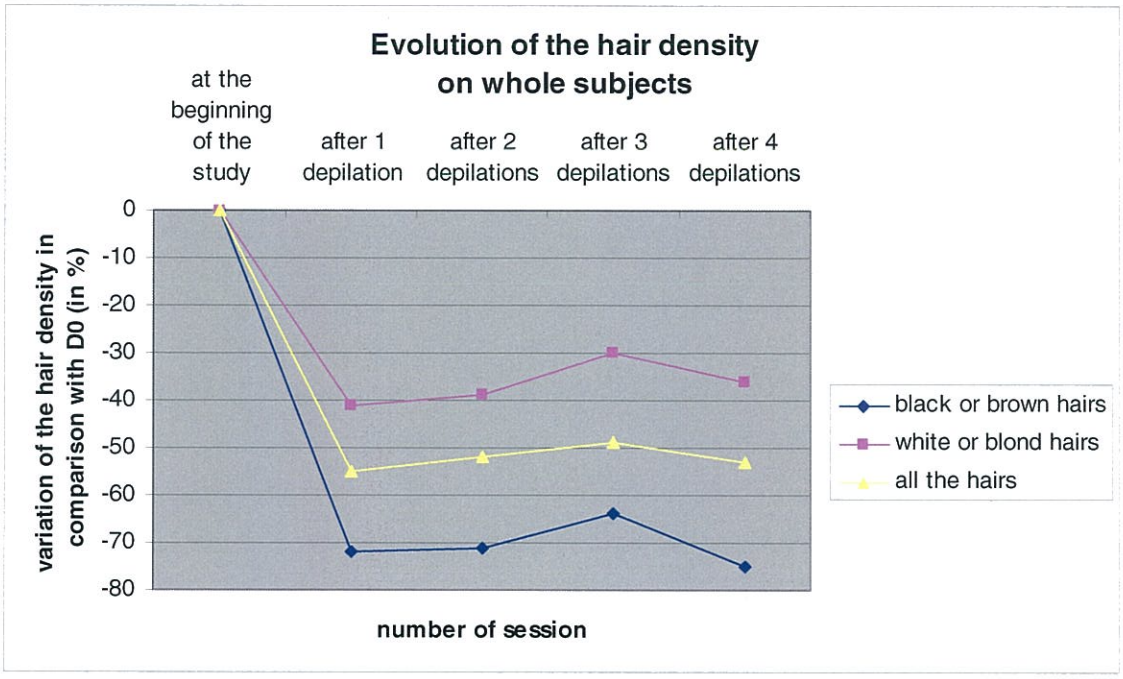
Tables below present a synthesis.

5.1.1. On all the subjects

Variation of the hair density after 1, 2, 3 and 4 photo-depilation sessions.
Comparison to before treatment

		Hair density (nb/cm²)		Student t test	
		Δ mean± SEM	Δ% on the mean	p	significant
After 1 session of photo-depilation (D42) n=14	**Black and brown hair**	-2.49±0.84	-72%	0.011	yes
	White and blond hair	-1.73±0.56	**-41%**	0.008	yes
	All the hair	-4.22±1.13	-55%	0.002	yes
After 2 sessions of photo-depilation (D84) n=14	**Black and brown hair**	-2.44±0.78	-71%	0.008	yes
	White and blond hair	-1.62±0.56	**-39%**	0.013	yes
	All the hair	-4.00±1.13	-52%	0.004	yes
After 3 sessions of photo-depilation (D126) n=12	**Black and brown hair**	-2.62±0.88	-64%	0.013	yes
	White and blond hair	-1.66±0.59	**-30%**	0.017	yes
	All the hair	-4.05±1.17	-49%	0.005	yes
After 4 sessions² of photo-depilation (D168) n=14	**Black and brown hair**	-2.59±0.99	-75%	0.023	yes
	White and blond hair	-1.55±0.52	**-36%**	0.012	yes
	All the hair	-4.14±1.29	-53%	0.008	yes

Illustration of the effect of the technique on hair re-growth



On all the subjects, the photo-depilation sessions allow to significantly decrease the hair density as of the first session (-55% on average).

More precisely, after a session of photo-depilation, a decrease in 72% on average of the density of the dark hair (black or brown) and in 41% of the light hair (white or blond) was observed.

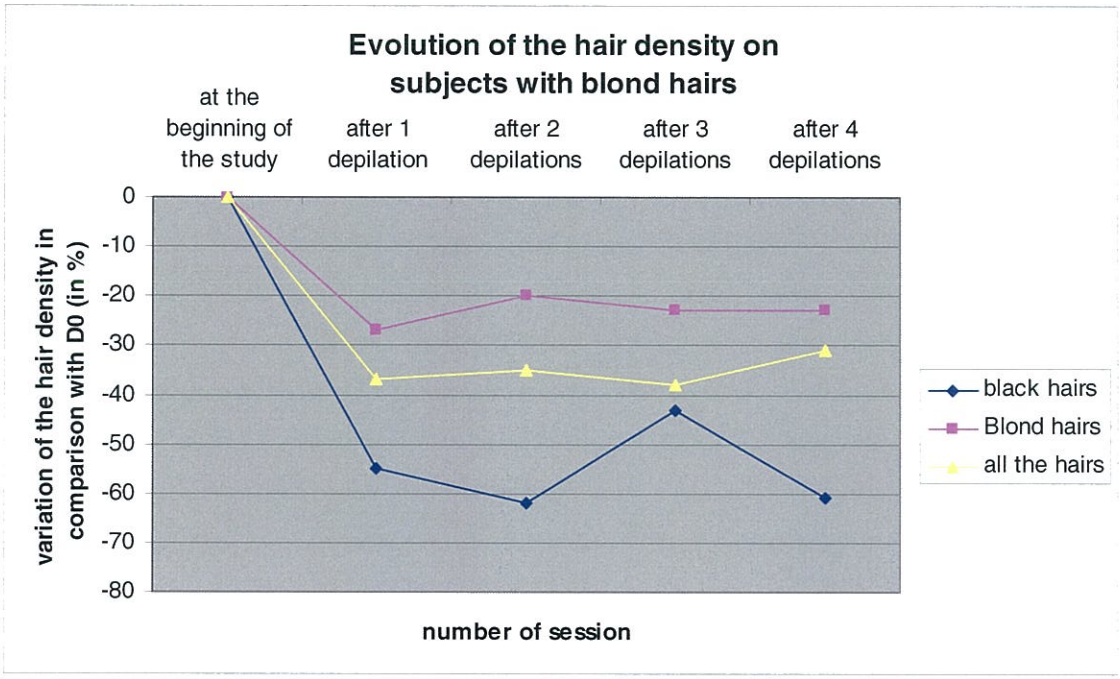
The following sessions allowed maintaining the hair density at the level reached after the first session, thus avoiding the return to the starting hair density.

5.1.2. On subjects with blond hair

Variation of the hair density after 1, 2, 3 and 4 photo-depilation sessions.
Comparison to before treatment

		Hair density (nb/cm²)	
		Δ mean± SEM	Δ% on the mean
After 1 session of photo-depilation (D42) n=7	**Chestnut hair**	-1.06±0.70	-55%
	Blond hair	-0.91±0.89	**-27%**
	All the hair (Chestnut and blond)	-1.97±1.30	-37%
After 2 sessions of photo-depilation (D84) n=7	**Chestnut hair**	-1.19±0.77	-62%
	Blond hair	-0.68±0.60	**-20%**
	All the hair (Chestnut and blond)	-1.87±0.96	-35%
After 3 sessions of photo-depilation (D126) n=6	**Chestnut hair**	-1.16±0.92	-43%
	Blond hair	-0.99±1.03	**-23%**
	All the hair (Chestnut and blond)	-2.03±1.35	-38%
After 4 sessions of photo-depilation (D168) n=7	**Chestnut hair**	--0.96±0.89	-61%
	Blond hair	-0.71±0.58	**-23%**
	All the hair (Chestnut and blond)	-1.67±1.17	-37%

Illustration of the effect of the technique on hair re-growth



On the subjects having blond hair, the sessions of photo-depilation made it possible to decrease the total hair density as of the first session (- 37% on average).

More precisely, after a session of photo-depilation, a decrease in 55% on average of the density of the dark hair (chestnut or brown) was observed. This hair density of the dark hair remained stable after the three following sessions.

The density of the clear hair (blond) was decreased after the first session (-27% on average) and was maintained after the following sessions.

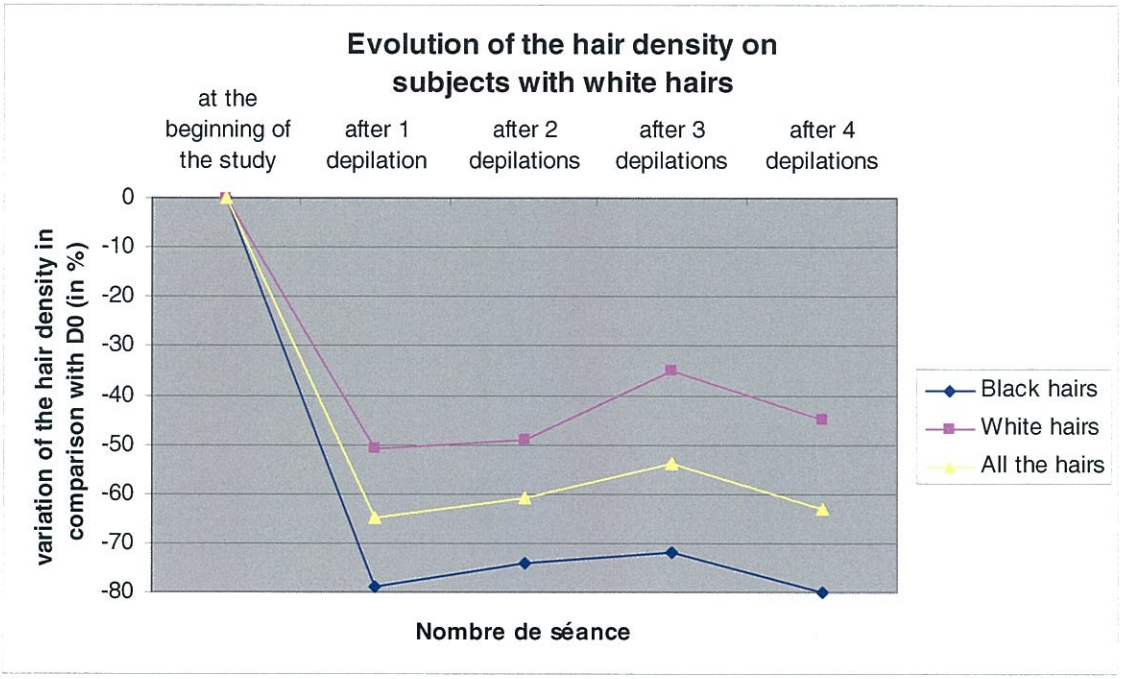
5.1.3. On subjects with blond hair

An illustration is presented in Appendices 9.5.

Variation of the hair density after 1, 2, 3 and 4 photo-depilation sessions.
Comparison to before treatment

		Hair density (nb/cm²)	
		Δ mean± SEM	**Δ% on the mean**
After 1 session of photo-depilation (D42) n=7	**Black hair**	-3.92±1.37	-79%
	White hair	-2.54±0.57	**-51%**
	All the hair (black and white)	-6.46±1.46	-65%
After 2 sessions of photo-depilation (D84) n=7	**Black hair**	-3.67±1.25	-74%
	White hair	-2.46±0.90	**-49%**
	All the hair (black and white)	-6.13±1.77	-61%
After 3 sessions of photo-depilation (D126) n=6	**Black hair**	-4.08±1.32	-72%
	White hair	-2.32±0.54	**-35%**
	All the hair (black and white)	± -6.39±1.57	-54%
After 4 sessions of photo-depilation (D168) n=7	**Black hair**	-3.98±1.55	-80%
	White hair	-2.27±0.76	**-45%**
	All the hair (black and white)	-6.25±1.90	-63%

Illustration of the effect of the technique on hair re-growth



On the subjects having white hair, a decrease of 51% of the total hair density was observed as of the first session with a maintain on this level until the end of the test.

The density of the dark hair was decreased in an important and progressive way after each session (of -62% after a session with -78% after 4 sessions).

The density of the white hair was decreased after the first session in -27% on average and was maintained on -45% after the fourth session.

5.2. Subjective evaluation questionnaire

The subjects' answers (in percentage) to the subjective evaluation questionnaire are presented in **Appendix 9.4**.

To be easier to read. the percentages were rounded off. The sum of these percentages may be different from 100%.
In this study (n=14). one subject represents 7.1 %.

The synthesis of the answers is presented in the table below.

EFFICACITÉ DE LA TECHNIQUE / *EFFICACY OF THIS TECHNIC*	
Technique efficace / *efficient technic* Très efficace / *very efficient* Efficace / efficient Assez efficace / *quite efficient*	**71%** 14% 36% 21%
Vous avez constaté l'efficacité de cette technique après : / *You saw the technic efficacy after:* La première séance / *the first session* La seconde séance / *the second session* La troisième séance / *the third session* La quatrième séance / *the fourth session*	 7% 43% 29% 7%
Après les 4 séances vous estimez qu'il reste / *after the four sessions, do you find that it remains :* Aucun poil / *No hair* Peu de poils / *a few hair* La moitié des poils / *Half of the hairs*	**86%** 7% 50% 29%
Satisfaction concernant l'efficacité du traitement / *satisfaction about treatment's efficacy* note moyenne/10 / *average mark/10* % de notes >5 / *% of marks >5*	 **6,1** 62%
SECURITE / *SECURITY*	
Absence de sensation désagréable pendant la photo-dépilation / No *unpleasant sensation during the photo-depilation*	**43%**
Sur une échelle de 0 à 10 (acceptable à non acceptable) pouvez-vous juger ces sensations ? *On a scale from 0 to 10 (acceptable to not acceptable), could you juged these sensations?* note moyenne/10 / *average mark/10* % de notes <5 / *% of marks <5*	 **2,1** 70%
UTILISATION ULTERIEURE DES PRODUITS / *FUTURE USE OF PRODUCTS*	
Seriez-vous prêt à utiliser cette technique sur une zone plus grande ?/ *Would you like to use this technic on a larger area?*	**50%**
A l'issue de cette étude seriez-vous prêt à aller en institut pour une épilation progressive et durable à l'aide de cette technologie ? / *At the end of this test, would you like to go in an institute to do a progressive and lasting depilation with this technology?* très certainement / *very certainly* certainement / *certainly*	**31%** 8% 23%

5.3. Safety

Some unpleasant effects were notified:

- Subject #6: 2nd degree burn after the D42 photo-depilation session due to a bad cooling of the zone before flashes. Persistence of a non-pigmentation of the zone after healing.
- Subject #16: 2nd degree burn after the D42 photo-depilation session due to a bad cooling of the zone before flashes.
- Subject #11: appearance of a brown spot after the first photo-depilation session and persistence during 13 days. Complete disappearance of the brown spot after a scrub.

In conclusion, on the 16 tested subjects, three subjects presented unpleasant feelings whose two are due to a bad cooling of the zones before the flashes.

6. CONCLUSION

This study had as primary objective to evaluate the evolution of the density of white and blond hair during four sessions of photo-depilation with Adéna device (D0. D42. D84 and D126).

The secondary objectives of this study were to evaluate:
- the evolution of the density of black hair on the studied zone (for the subjects with some),
- the subjective appreciation of its efficacy, its tolerance and its benefit.

Study conditions:

Product	**Reference:** Adéna Device	**Form:** Hair pulse photo-depilation device	
Experimental plan	- Open and intra-individual study.		
Assessment criteria	• Study of the variations of the light hair (white and blond) and dark hair (black and brown) density by images acquisition with videomicroscope Hirox® and analysis using Photoshop CS3® software.	**Kinetics**	D0. D42. D84. D126 and D168
		Methodology	Before / After
		Measurement zone	Legs or thorax
		Application frequency	4 sessions spaced of 42 days
	• Subjective evaluation (questionnaire).	**Kinetics**	D168
		Methodology	Before / After
		Measurement zone	Legs or thorax
		Application frequency	4 sessions spaced of 42 days
Studied population	Number of subjects analyzed: - for the study of the hairs density: 14 on D42, 14 on D84, 12 on D126 and 14 on D168. - for subjective evaluation: 14.		
	Average age: 50±5 years (between 23 and 76).		
	Main inclusion criteria: Sexe: female or male Age: 18 years old and more. Phototype : I to III. 8 subjects with blond hair agreeing to have a shaved zone of 15 cm² (5 cm X 3 cm) 8 subjects with white hair agreeing to have a shaved zone of 15 cm² (5 cm X 3 cm)		

Under the conditions of the study, the photo-depilation sessions induced:

- **a significant effect on hair growth characterized by a significant decrease in the total hair density from the first session (-55% on average).**
  After one session, a decrease in 72% of dark hair and 41% of clear hair (white or blond) was observed.
  More precisely, on clear hair, 27% of blond hair and 51% of white hair disappeared.
  During the following sessions, the effects were maintained on dark and white hair (respectively -75% and -45% after four sessions).

- **a satisfaction of the majority of the subjects for its efficacy. 71% of the subjects have esteemed that the technical was efficient and 61% have attributed a note ≥5 on an efficacy scale range from 0 to 10.**
  57% of the subjects have noticed that after four sessions, few or none hair hava grown.
  Regarding confort, 43% of the subjects did not felt any unpleasant sensation during the photo-depilation sessions and 70% have attributed a note <2 on a pain scale range from 0 to 10. 50% of the subjects would continue this technical on a largest zone.

7. CERTIFICATION

The study was conducted according to Helsinki Declaration (1964) and its successive updates. Data were obtained using the study protocol. current internal procedures and in the spirit of the note for guidance on Good Clinical Practice CPMP / ICH / 135 / 95. January 1997 (ref: 1 to 4 in §8.1).

Only the hard copy of the report (color bands) transmitted by Dermscan can be considered as the original and official document. Digitally-produced or electronic documents transmitted by Dermscan are not protected by an electronic signature. according to Law n°2000-230 dates March 13. 2000 and its applicable decrees. The contents of digitally-produced or electronic documents in no means engage the responsibility of Dermscan.
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This study was totally performed under the responsibility of Dermscan.

Dermscan quality system is certified ISO 9001: 2008.

All the observations and numerical data collected throughout the study are reported in this document. I certify that these data are in accordance with the obtained results.

Date and signature:

February 11, 2011

Name **Cécile CHARMEL**
Function Trial Manager Assistant

8. BIBLIOGRAPHY

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8.2. Data analysis

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9. APPENDICES

9.1. Hair density on all the subjects

Subjects	surface (cm²)	D0			D42			D84			D126			D168		
		number of hairs before coloration (black and brown hairss)	number of hairs after coloration (black or brown + blond or white)	number of blond or white hairs	number of hairs before coloration (black and brown hairss)	number of hairs after coloration (black or brown + blond or white)	number of blond or white hairs	number of hairs before coloration (black and brown hairss)	number of hairs after coloration (black or brown + blond or white)	number of blond or white hairs	number of hairs before coloration (black and brown hairss)	number of hairs after coloration (black or brown + blond or white)	number of blond or white hairs	number of hairs before coloration (black and brown hairss)	number of hairs after coloration (black or brown + blond or white)	number of blond or white hairs
1	4.79	1	6	5	1	26	25	2	12	10	0	15	15	0	8	8
2	3.89	0	8	8	2	2	0	5	8	3	mv	3	mv	5	4	-1
3	4.84	74	102	28	18	37	19	26	40	14	27	42	15	12	29	17
4	4.03	20	41	21	4	16	12	4	13	9	2	17	15	6	11	5
5	5.67	11	59	48	1	23	22	4	20	16	4	34	30	3	43	40
7	4.25	1	4	3	1	3	2	0	2	2	1	4	3	0	3	3
8	4.9	10	18	8	0	4	4	6	18	12	mv	mv	mv	0	9	9
9	4.97	5	20	15	1	12	11	0	18	18	0	15	15	1	14	13
10	4.47	10	50	40	3	31	28	7	30	23	5	22	17	3	34	31
11	5.27	9	22	13	10	14	4	3	19	16	18	33	15	9	27	18
12	5.52	34	67	33	8	20	12	2	12	10	5	20	15	9	11	2
13	5.96	35	63	28	7	24	17	8	31	23	7	30	23	5	24	19
14	4.9	16	34	18	7	15	8	0	17	17	3	9	6	mv	mv	mv
15	5.75	19	48	29	4	12	8	2	14	12	3	13	10	3	18	15

mv : missing value

subjects	D0 density of black or brown hairs (nb/cm²)	D0 density of blond or white hairs (nb/cm²)	D42 density of black or brown hairs (nb/cm²)	D42 density of blond or white hairs (nb/cm²)	D84 density of black or brown hairs (nb/cm²)	D84 density of blond or white hairs (nb/cm²)	D126 density of black or brown hairs (nb/cm²)	D126 density of blond or white hairs (nb/cm²)	D168 density of black or brown hairs (nb/cm²)	D168 density of blond or white hairs (nb/cm²)	variations (D42-D0) density of black or brown hairs (nb/cm²)	variations (D42-D0) density of blond or white hairs (nb/cm²)	variations (D84-D0) density of black or brown hairs (nb/cm²)	variations (D84-D0) density of blond or white hairs (nb/cm²)	variations (D126-D0) density of black or brown hairs (nb/cm²)	variations (D126-D0) density of blond or white hairs (nb/cm²)	variations (D168-D0) density of black or brown hairs (nb/cm²)	variations (D168-D0) density of blond or white hairs (nb/cm²)
1	0.21	1.04	0.21	5.22	0.42	2.09	0.00	3.13	0.00	1.67	0.00	4.18	0.21	1.04	-0.21	2.09	-0.21	0.63
2	0.00	2.06	0.51	0.00	1.29	0.77	mv	mv	1.29	-0.26	0.51	-2.06	1.29	-1.29	mv	mv	1.29	-2.31
3	15.29	5.79	3.72	3.93	5.37	2.89	5.58	3.10	2.48	3.51	-11.57	-1.86	-9.92	-2.89	-9.71	-2.69	-12.81	-2.27
4	4.96	5.21	0.99	2.98	0.99	2.23	0.50	3.72	1.49	1.24	-3.97	-2.23	-3.97	-2.98	-4.47	-1.49	-3.47	-3.97
5	1.94	8.47	0.18	3.88	0.71	2.82	0.71	5.29	0.53	7.05	-1.76	-4.59	-1.23	-5.64	-1.23	-3.17	-1.41	-1.41
7	0.24	0.71	0.24	0.00	0.00	0.47	0.24	mv	0.00	0.71	0.00	-0.24	-0.24	-0.24	0.00	0.00	-0.24	0.00
8	2.04	1.63	0.00	0.82	1.22	2.45	mv	mv	0.00	1.84	-2.04	-0.82	-0.82	0.82	mv	mv	-2.04	0.20
9	1.01	3.02	0.20	2.21	0.00	3.62	0.00	3.02	0.20	2.62	-0.80	-0.80	-1.01	0.60	-1.01	0.00	-0.80	-0.40
10	2.24	8.95	0.67	6.26	1.57	5.15	1.12	3.80	0.67	6.94	-1.57	-2.68	-0.67	-3.80	-1.12	-5.15	-1.57	-2.01
11	1.71	2.47	1.90	0.76	0.45	2.39	3.42	2.85	1.71	3.42	0.19	-1.71	-1.26	-0.08	1.71	0.38	0.00	0.95
12	6.16	5.98	1.45	2.17	0.36	1.81	0.91	2.72	1.63	0.36	-4.71	-3.80	-5.80	-4.17	-5.25	-3.26	-4.53	-5.62
13	5.87	4.70	1.17	2.85	1.34	3.86	1.17	3.86	0.84	3.19	-4.70	-1.85	-4.53	-0.84	-4.70	-0.84	-5.03	-1.51
14	3.27	3.67	1.43	1.63	0.00	3.47	0.61	1.22	mv	mv	-1.84	-2.04	-3.27	-0.20	-2.65	-2.45	mv	mv
15	3.30	5.04	0.70	1.39	0.35	2.09	0.52	1.74	0.52	2.61	-2.61	-3.65	-2.96	-2.96	-2.78	-3.30	-2.78	-2.43
Mean	**3.44**	**4.19**	**0.95**	**2.47**	**1.00**	**2.58**	**1.23**	**3.80**	**0.87**	**2.68**	**-2.49**	**-1.73**	**-2.44**	**-1.62**	**-2.62**	**-1.66**	**-2.59**	**-1.55**
Mediane	2.14	4.19	0.68	2.19	0.58	2.42	0.66	3.06	0.67	2.61	-1.80	-1.95	-1.25	-1.06	-1.94	-1.97	-1.57	-1.51
Minimum	0.00	0.71	0.00	0.00	0.00	0.47	0.00	0.71	0.00	-0.26	-11.57	-4.59	-9.92	-5.64	-9.71	-5.15	-12.81	-5.62
Maximum	15.29	8.95	3.72	6.26	5.37	5.15	5.58	5.29	2.48	7.05	0.51	4.18	1.29	1.04	1.71	2.09	1.29	0.95
SEM	**1.06**	**0.69**	**0.26**	**0.49**	**0.36**	**0.32**	**0.47**	**0.36**	**0.22**	**0.62**	**0.84**	**0.56**	**0.78**	**0.56**	**0.88**	**0.59**	**0.99**	**0.52**
95% CI	2.28	1.49	0.57	1.06	0.79	0.70	1.04	0.80	0.48	1.36	1.81	1.20	1.69	1.22	1.95	1.30	2.16	1.13
										Δ%	**-72**	**-41**	**-71**	**-39**	**-64**	**-30**	**-75**	**-36**
										P =	**0.011**	**0.008**	**0.008**	**0.013**	**0.013**	**0.017**	**0.023**	**0.012**

mv : missing value

Laboratoire Dermscan

	Pilar density (nb/cm²)					variations of the pilar density			
subjects	D0	D42	D84	D126	D168	D42-D0	D84-D0	D126-D0	D168-D0
1	1.25	5.43	2.51	3.13	1.67	4.18	1.25	1.88	0.42
2	2.06	0.51	2.06	0.77	1.03	-1.54	0.00	-1.29	-1.03
3	21.07	7.64	8.26	8.68	5.99	-13.43	-12.81	-12.40	-15.08
4	10.17	3.97	3.23	4.22	2.73	-6.20	-6.95	-5.96	-7.44
5	10.41	4.06	3.53	6.00	7.58	-6.35	-6.88	-4.41	-2.82
7	0.94	0.71	0.47	0.94	0.71	-0.24	-0.47	0.00	-0.24
8	3.67	0.82	3.67	mv	1.84	-2.86	0.00	mv	-1.84
9	4.02	2.41	3.62	3.02	2.82	-1.61	-0.40	-1.01	-1.21
10	11.19	6.94	6.71	4.92	7.61	-4.25	-4.47	-6.26	-3.58
11	4.17	2.66	3.61	6.26	5.12	-1.52	-0.57	2.09	0.95
12	12.14	3.62	2.17	3.62	1.99	-8.51	-9.96	-8.51	-10.14
13	10.57	4.03	5.20	5.03	4.03	-6.54	-5.37	-5.54	-6.54
14	6.94	3.06	3.47	1.84	mv	-3.88	-3.47	-5.10	mv
15	8.35	2.09	2.43	2.26	3.13	-6.26	-5.91	-6.09	-5.22
Mean	**7.64**	**3.42**	**3.64**	**3.90**	**3.56**	**-4.22**	**-4.00**	**-4.05**	**-4.14**
Mediane	7.64	3.34	3.50	3.62	2.82	-4.06	-3.97	-5.10	-2.82
Minimum	0.94	0.51	0.47	0.77	0.71	-13.43	-12.81	-12.40	-15.08
Maximum	21.07	7.64	8.26	8.68	7.61	4.18	1.25	2.09	0.95
SEM	**1.47**	**0.58**	**0.53**	**0.63**	**0.65**	**1.13**	**1.13**	**1.17**	**1.29**
95% CI	3.18	1.26	1.14	1.38	1.42	2.43	2.44	2.54	2.82
					Δ%	**-55**	**-52**	**-49**	**-53**
					p =	**0.002**	**0.004**	**0.005**	**0.008**

mv : missing value

9.2. Hair density on subjects with blond hair

		D0			D42			D84			D126			D168		
subjects	surface (cm²)	number of hairs before coloration (brown hairss)	number of hairs after coloration (brown and blond hairss)	number of blond hairs	number of hairs before coloration (brown hairss)	number of hairs after coloration (brown and blond hairss)	number of blond hairs	number of hairs before coloration (brown hairss)	number of hairs after coloration (brown and blond hairss)	number of blond hairs	number of hairs before coloration (brown hairss)	number of hairs after coloration (brown and blond hairss)	number of blond hairs	number of hairs before coloration (brown hairss)	number of hairs after coloration (brown and blond hairss)	number of blond hairs
1	4.79	1	6	5	1	26	25	2	12	10	0	15	15	0	8	8
2	3.89	0	8	8	2	2	0	5	8	3	mv	3	mv	5	4	-1
7	4.25	1	4	3	1	3	2	0	2	2	1	4	3	0	3	3
10	4.47	10	50	40	3	31	28	7	30	23	5	22	17	3	34	31
11	5.27	9	22	13	10	14	4	3	19	16	18	33	15	9	27	18
13	5.96	35	63	28	7	24	17	8	31	23	7	30	23	5	24	19
14	4.9	16	34	18	7	15	8	0	17	17	3	9	6	mv	mv	mv

	D0		D42		D84		D126		D168		variations (D42-D0)		variations (D84-D0)		variations (D126-D0)		variations (D168-D0)	
subjects	density of brown hairs (nb/cm²)	density of blond hairs (nb/cm²)	density of brown hairs (nb/cm²)	density of blond hairs (nb/cm²)	density of brown hairs (nb/cm²)	density of blond hairs (nb/cm²)	density of brown hairs (nb/cm²)	density of blond hairs (nb/cm²)	density of brown hairs (nb/cm²)	density of blond hairs (nb/cm²)	density of brown hairs (nb/cm²)	density of blond hairs (nb/cm²)	density of brown hairs (nb/cm²)	density of blond hairs (nb/cm²)	density of brown hairs (nb/cm²)	density of blond hairs (nb/cm²)	density of brown hairs (nb/cm²)	density of blond hairs (nb/cm²)
1	0.21	1.04	0.21	5.22	0.42	2.09	0.00	3.13	0.00	1.67	0.00	4.18	0.21	1.04	-0.21	2.09	-0.21	0.63
2	0.00	2.06	0.51	0.00	1.29	0.77	mv	mv	1.29	-0.26	0.51	-2.06	1.29	-1.29	mv	mv	1.29	-2.31
7	0.24	0.71	0.24	0.47	0.00	0.47	0.24	0.71	0.00	0.71	0.00	-0.24	-0.24	-0.24	0.00	0.00	-0.24	0.00
10	2.24	8.95	0.67	6.26	1.57	5.15	1.12	3.80	0.67	6.94	-1.57	-2.68	-0.67	-3.80	-1.12	-5.15	-1.57	-2.01
11	1.71	2.47	1.90	0.76	0.57	3.04	3.42	2.85	1.71	3.42	0.19	-1.71	-1.14	0.57	1.71	0.38	0.00	0.95
13	5.87	4.70	1.17	2.85	1.34	3.86	1.17	3.86	0.84	3.19	-4.70	-1.85	-4.53	-0.84	-4.70	-0.84	-5.03	-1.51
14	3.27	3.67	1.43	1.63	0.00	3.47	0.61	1.22	mv	mv	-1.84	-2.04	-3.27	-0.20	-2.65	-2.45	mv	mv
Mean	**1.93**	**3.37**	**0.88**	**2.46**	**0.74**	**2.69**	**1.09**	**2.60**	**0.75**	**2.61**	**-1.06**	**-0.91**	**-1.19**	**-0.68**	**-1.16**	**-0.99**	**-0.96**	**-0.71**
Mediane	1.71	2.47	0.67	1.63	0.57	3.04	0.87	2.99	0.76	2.43	0.00	-1.85	-0.67	-0.24	-0.66	-0.42	-0.22	-0.76
Minimum	0.00	0.71	0.21	0.00	0.00	0.47	0.00	0.71	0.00	-0.26	-4.70	-2.68	-4.53	-3.80	-4.70	-5.15	-5.03	-2.31
Maximum	5.87	8.95	1.90	6.26	1.57	5.15	3.42	3.86	1.71	6.94	0.51	4.18	1.29	1.04	1.71	2.09	1.29	0.95
SEM	**0.80**	**1.07**	**0.24**	**0.92**	**0.25**	**0.64**	**0.50**	**0.54**	**0.28**	**1.04**	**0.70**	**0.89**	**0.77**	**0.60**	**0.92**	**1.03**	**0.89**	**0.58**
95% CI	1.96	2.62	0.59	2.26	0.61	1.56	1.29	1.40	0.72	2.67	1.70	2.19	1.88	1.47	2.36	2.64	2.30	1.48
										Δ%	**-55**	**-27**	**-62**	**-20**	**-43**	**-23**	**-61**	**-23**

mv : missing value

	Brown and blond hairs density (nb/cm²)								
subjects	D0	D42	D84	D126	D168	D42-D0	D84-D0	D126-D0	D168-D0
1	1.25	5.43	2.51	3.13	1.67	4.18	1.25	1.88	0.42
2	2.06	0.51	2.06	0.77	1.03	-1.54	0.00	-1.29	-1.03
7	0.94	0.71	0.47	0.94	0.71	-0.24	-0.47	0.00	-0.24
10	11.19	6.94	6.71	4.92	7.61	-4.25	-4.47	-6.26	-3.58
11	4.17	2.66	3.61	6.26	5.12	-1.52	-0.57	2.09	0.95
13	10.57	4.03	5.20	5.03	4.03	-6.54	-5.37	-5.54	-6.54
14	6.94	3.06	3.47	1.84	mv	-3.88	-3.47	-5.10	mv
Mean	**5.30**	**3.33**	**3.43**	**3.27**	**3.36**	**-1.97**	**-1.87**	**-2.03**	**-1.67**
Mediane	4.17	3.06	3.47	3.13	2.85	-1.54	-0.57	-1.29	-0.63
Minimum	0.94	0.51	0.47	0.77	0.71	-6.54	-5.37	-6.26	-6.54
Maximum	11.19	6.94	6.71	6.26	7.61	4.18	1.25	2.09	0.95
SEM	**1.63**	**0.89**	**0.78**	**0.82**	**1.11**	**1.30**	**0.96**	**1.35**	**1.17**
95% CI	4.00	2.18	1.90	2.02	2.85	3.18	2.34	3.30	3.01
					Δ%	**-37**	**-35**	**-38**	**-37**

mv : missing value

9.3. Hair density on subjects with white hair

subjects	surface (cm²)	D0			D42			D84			D126			D168		
		number of hairs before coloration (dark hairss)	number of hairs after coloration (dark and white hairss)	number of white hairs	number of hairs before coloration (dark hairss)	number of hairs after coloration (dark and white hairss)	number of white hairs	number of hairs before coloration (dark hairss)	number of hairs after coloration (dark and white hairss)	number of white hairs	number of hairs before coloration (dark hairss)	number of hairs after coloration (dark and white hairss)	number of white hairs	number of hairs before coloration (dark hairss)	number of hairs after coloration (dark and white hairss)	number of white hairs
3	4.84	74	102	28	18	37	19	26	40	14	27	42	15	12	29	17
4	4.03	20	41	21	4	16	12	4	13	9	2	17	15	6	11	5
5	5.67	11	59	48	1	23	22	4	20	16	4	34	30	3	43	40
8	4.9	10	18	8	0	4	4	6	18	12	mv	mv	mv	0	9	9
9	4.97	5	20	15	1	12	11	0	18	18	0	15	15	1	14	13
12	5.52	34	67	33	8	20	12	2	12	10	5	20	15	9	11	2
15	5.75	19	48	29	4	12	8	2	14	12	3	13	10	3	18	15

mv: missing value

subjects	D0	D42		D84		D126		D168		variations (D42-D0)		variations (D84-D0)		variations (D126-D0)		variations (D168-D0)	
	density of dark hairs (nb/cm²)	density of white hairs (nb/cm²)	density of dark hairs (nb/cm²)	density of white hairs (nb/cm²)	density of dark hairs (nb/cm²)	density of white hairs (nb/cm²)	density of dark hairs (nb/cm²)	density of white hairs (nb/cm²)	density of dark hairs (nb/cm²)	density of white hairs (nb/cm²)	density of dark hairs (nb/cm²)	density of white hairs (nb/cm²)	density of dark hairs (nb/cm²)	density of white hairs (nb/cm²)	density of dark hairs (nb/cm²)	density of white hairs (nb/cm²)	density of dark hairs (nb/cm²)	density of white hairs (nb/cm²)
3	15.29	5.79	3.72	3.93	5.37	2.89	5.58	3.10	2.48	3.51	-11.57	-1.86	-9.92	-2.89	-9.71	-2.69	-12.81	-2.27
4	4.96	5.21	0.99	2.98	0.99	2.23	0.50	3.72	1.49	1.24	-3.97	-2.23	-3.97	-2.98	-4.47	-1.49	-3.47	-3.97
5	1.94	8.47	0.18	3.88	0.71	2.82	0.71	5.29	0.53	7.05	-1.76	-4.59	-1.23	-5.64	-1.23	-3.17	-1.41	-1.41
8	2.04	1.63	0.00	0.82	1.22	2.45	mv	mv	0.00	1.84	-2.04	-0.82	-0.82	0.82	mv	mv	-2.04	0.20
9	1.01	3.02	0.20	2.21	0.00	3.62	0.00	3.02	0.20	2.62	-0.80	-0.80	-1.01	0.60	-1.01	0.00	-0.80	-0.40
12	6.16	5.98	1.45	2.17	0.36	1.81	0.91	2.72	1.63	0.36	-4.71	-3.80	-5.80	-4.17	-5.25	-3.26	-4.53	-5.62
15	3.30	5.04	0.70	1.39	0.35	2.09	0.52	1.74	0.52	2.61	-2.61	-3.65	-2.96	-2.96	-2.78	-3.30	-2.78	-2.43
Mean	**4.96**	**5.02**	**1.03**	**2.48**	**1.29**	**2.56**	**1.37**	**3.26**	**0.98**	**2.75**	**-3.92**	**-2.54**	**-3.67**	**-2.46**	**-4.08**	**-2.32**	**-3.98**	**-2.27**
Mediane	3.30	5.21	0.70	2.21	0.71	2.45	0.61	3.06	0.53	2.61	-2.61	-2.23	-2.96	-2.96	-3.62	-2.93	-2.78	-2.27
Minimum	1.01	1.63	0.00	0.82	0.00	1.81	0.00	1.74	0.00	0.36	-11.57	-4.59	-9.92	-5.64	-9.71	-3.30	-12.81	-5.62
Maximum	15.29	8.47	3.72	3.93	5.37	3.62	5.58	5.29	2.48	7.05	-0.80	-0.80	-0.82	0.82	-1.01	0.00	-0.80	0.20
SEM	**1.85**	**0.83**	**0.49**	**0.45**	**0.70**	**0.23**	**0.85**	**0.48**	**0.34**	**0.82**	**1.37**	**0.57**	**1.25**	**0.90**	**1.32**	**0.54**	**1.55**	**0.76**
95% CI	4.53	2.03	1.19	1.10	1.71	0.56	2.19	1.24	0.84	2.00	3.35	1.39	3.05	2.20	3.40	1.39	3.78	1.87
										Δ%	**-79**	**-51**	**-74**	**-49**	**-72**	**-35**	**-80**	**-45**

mv: missing value

subjects	dark and white hairs density (nb/cm²)						
	D0	D42	D84	D126	D168	D84-D0	D126-D0	D168-D0
3	21.07	7.64	8.26	8.68	5.99	-12.81	-12.40	-15.08
4	10.17	3.97	3.23	4.22	2.73	-6.95	-5.96	-7.44
5	10.41	4.06	3.53	6.00	7.58	-6.88	-4.41	-2.82
8	3.67	0.82	3.67	mv	1.84	0.00	mv	-1.84
9	4.02	2.41	3.62	3.02	2.82	-0.40	-1.01	-1.21
12	12.14	3.62	2.17	3.62	1.99	-9.96	-8.51	-10.14
15	8.35	2.09	2.43	2.26	3.13	-5.91	-6.09	-5.22
Mean	**9.98**	**3.52**	**3.85**	**4.63**	**3.73**	**-6.13**	**-6.39**	**-6.25**
Mediane	10.17	3.62	3.53	3.92	2.82	-6.26	-6.02	-5.22
Minimum	3.67	0.82	2.17	2.26	1.84	-13.43	-12.81	-12.40	-15.08
Maximum	21.07	7.64	8.26	8.68	7.58	-1.61	0.00	-1.01	-1.21
SEM	**2.21**	**0.82**	**0.77**	**0.96**	**0.83**	**1.46**	**1.77**	**1.57**	**1.90**
95% CI	5.42	2.00	1.88	2.47	2.03	3.57	4.32	4.03	4.66
					Δ%	**-65**	**-61**	**-54**	**-63**

9.4. Subjective evaluation questionnaire

EFFICACITÉ DE LA TECHNIQUE / *EFFICACY OF THIS TECHNIC*

1 Globalement avez-vous trouvé cette technique efficace ? / *Globally, did you find this technic efficient ?*

Très efficace / *very efficient*	14%
Efficace / *efficient*	36%
Assez efficace / *quite fficient*	21%
Peu efficace / little efficient	21%
Pas efficace / *not efficient*	7%

2 Après combien de séances avez-vous constaté l'efficacité de cette technique / *After how many sessions, did you see the technic efficacy:*

La première / *the first*	7%
La seconde / *the second*	43%
La troisième / *the third*	29%
La quatrième / *the fourth*	7%
Jamais / *never*	14%

3 Après les 4 séances vous estimez qu'il reste / *After the four sessions, do you find that it remains:*

Aucun poil / *No hair*	7%
Peu de poils / *Few hair*	50%
La moitié des poils / *Half of the hair*	29%
Presque tous les poils / *Almost all hair*	7%
Tous les poils / *all hairs*	7%

4 Sur une échelle de 0 à 10 pouvez-vous estimer votre satisfaction concernant l'efficacité du traitement ? *On a 0 to 10 scale, could you juged your satisfaction about the treatment efficacy?*

Traitement inefficace / *Not efficient treatment*									Traitement efficace / *Efficient treatment*	
0	1	2	3	4	5	6	7	8	9	10
0%	0%	15%	0%	23%	0%	15%	31%	15%	0%	0%

SECURITE/*SECURITY*

5 Lors de la photo-dépilation avez-vous ressenti des sensations désagréables : *During the photo-depilation, did you feel any unpleasant sensations?*

oui / *yes*	57%
non / no	43%

Si oui, précisez : / *If yes, precise:*

.....

6 Sur une échelle de 0 à 10 pouvez-vous juger les sensations ressenties lors des séances ? *On a scale from to 10 could you judge the sensations felt during the sessions?*

Sensation acceptable / *Acceptable sensation*									Sensation inacceptable / *Intolerable sensation*	
0	1	2	3	4	5	6	7	8	9	10
40%	30%	0%	0%	20%	0%	10%	0%	0%	0%	0%

UTILISATION ULTERIEURE / *FUTURE USE*

7 Seriez-vous prêt à utiliser cette technique sur une zone plus grande ?/ *Would you like to use this technic on a larger area?*

oui / *yes*	50%
non / no	50%

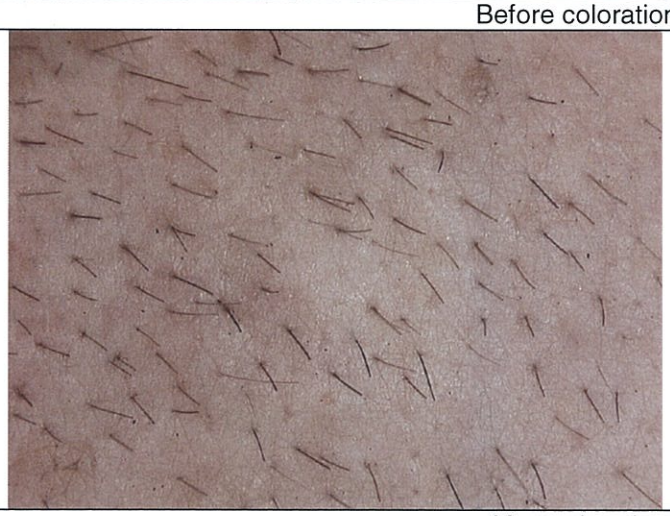
8 A l'issue de cette étude, seriez-vous prêt à aller en institut pour une épilation progressive et durable à l'aide de cette technologie ? / *At the end of this study would you like to go in an institute to do a progressive and lasting depilation with this technology,?*

très certainement / *very certainly*	8%
certainement /	23%
probablement pas / *probably not*	38%
certainement pas / *certainly not*	31%

Sujets / *Subjects*	**Q5 : Sensations désagréables ressenties /** *Unpleasant sensations felt*	**Q8 : Commentaires /** *Comments*
1	**Sensation d'inconfort ressentie au moment du flash, pendant la photo-depilation.** / *Discomfort sensation felt at the flash, during the photo-depilation.*	**N'ayant pas une pilosité très développée, le système de photo-dépilation serait superflu.** / My pilar density being not important, this depilation system won't be necessary.
2	-	-
3	-	**Après réflexion, je ferai bien une épilation progressive et durable à l'aide de cette technologie en institut.** / *After thought, I could do a progressive and lasting depilation in an institute with this technology.*
4	-	-
5	-	-
(6)*	**(Brûlure suite au J42 puis dépigmentation de la zone toujours présente à J126 => Sortie d'essai à J126)*** / *(Burn after D42 and depigmentation on the zone still present on D126 => Dropped out on D126)**	
7	-	-
8	-	-
9	-	-
10	-	-
11	-	-
12	-	-
13	-	-
14	-	-
15	-	-
(16)*	**(Brûlure au second degré le 10 septembre 2009 => Sortie d'essai à J46)*** / *(Second-degree burn on September 10, 2009 => Dropped out on D46)**	

9.5. Illustrations

Illustration of the effect of the photo-depilation device, on subject #4 which presented white hair.

Before photo-depilation sessions (D0)	After 4 sessions of photo-depilation (D168)
Before coloration of the white hair	
	
After coloration of the white hair	