October 18, 2001

Dockets Management Branch
Division of Management Systems and Policy
Office of Human Resources and Management Services
Food and Drug Administration
12420 Parklawn Drive (HFA-305)
Room l-23
Rockville, MD 20857

VIA FEDERAL EXPRESS

Dear Sir or Madam:

Please find enclosed a Petition for Administrative Reconsideration in the 5 10(k) decision for Docket K8925 14: Epilator 629 by American Hair Removal System Co. (AHRS).

This petition shows that FDA's decision was based on false and misleading submission data. In light of statements in the 28 October 1998 Final Rule in Docket 97N-0199 and in light of submission data of disputed authorship, this clearance warrants reconsideration.

Please do not hesitate to call if you require anything else to help resolve this matter in favor of consumers.

Sincerely,

Andrea James

P.O. Box 132 17
Chicago, IL 60613
773-528-2462

Petition for Reconsideration
Docket No. K892514

AHRS Epilator 629
manufactured by American Hair Removal System (AHRS)
Regulation Number: 878.5360
Product Code: KCX
Prepared as stipulated in 21 CFR 10.33

Submitted on October 18, 2001
by Andrea James

Petition for Reconsideration: Docket No. KS92514

The undersigned submits this petition for reconsideration of the 510(k) decision of the Commissioner of Food and Drugs in Docket No. K892514, the American Hair Removal System (AHRS) Epilator 629.

A. Decision involved

This petition requests reconsideration of the following:

1. Device identification and intended use.

2. Device labeling claims.

B. Action requested

1. Rescission of AHRS clearance as "intended to destroy the roots of unwanted hair for the purpose of permanent hair removal."

2. Prohibition of express or implied AHRS labeling and promotional claims of permanent hair removal.

C. Statement of grounds

The following reasons demonstrate good cause for special reconsideration at this time under 21 CFR 10.33:

> AHRS submitted comparative data which was falsified. Enclosed documents indicate the data submitted in 1990 by AHRS were copyrighted by a rival in 1987. AHRS clearance to market as permanent hair removal was based on this data. This makes the AHRS submission in violation of 21 CFR 807.87(k), requiring that submissions are "truthful and accurate and that no material fact has been omitted."

This petition is put forth in good faith on sound public policy grounds, demonstrating relevant information not adequately considered. I respectfully ask you to reconsider this decision in the interest of good science and justice, and especially in the interest of U.S. consumers.

October 18, 2001

Background

The American Hair Removal System (AHRS) Epilator 629 was cleared to market on 14 August 1990 in Docket K8925 14. In this decision, the manufacturer was cleared to make promotional claims of permanent hair removal based on submitted data allegedly comparing the AHRS device to predicate needle-type epilators.

However, another tweezer-type epilator maker claims that the comparative data submitted by AHRS are plagiarized promotional materials originally copyrighted in 1987, three years before AHRS submitted them as their own to FDA.

Stephens Manufacturing, maker of the Guaranty Hair Removal (GHR) tweezer-type epilator, shows that two comparative tests submitted by AHRS were stolen almost verbatim from GHR clinical studies. Inventor Judith Stephens currently uses this copyrighted data from 1987 on at least two GHR promotional websites:

http://www.hairfree.com/studies.htm
http://www.consumerbeware.com/ghr_studies.htm

These two tests conducted by GHR were the basis of FDA clearance for AHRS to claim permanent hair removal.

Enclosed evidence

1. AHRS data as submitted to FDA
2. GHR data "Copyright © 1987" with passages identical to AHRS highlighted
3. FDA clearance in Docket K892514 citing data stolen by AHRS

Based on this evidence, this petition requests that AHRS clearance to make claims of permanent hair removal based on disputed comparative data be rescinded.

Side-by-side comparison

Left side
AHRS 1990 submission

Right side
GHR materials marked "Copyright 01987"

(identical passages highlighted)

From GHR promotional material marked "Copyright ©1987." Passages identical to AHRS submission are highlighted.

COMPARISON OF THE EFFECTIVENESS OF NEEDLE AND NO-NEEDLE ELECTROLYSIS

Abstract: Qe compared the effectiveness of hair epilation using two electrolysis devices, a needle epilator and a no-needle epilator. The study was designed to comply with the standards set forth by the International Guild of Electrologists, Inc. The average number of hairs that regrew with the needle epiletor was 29; the average regrowth with the no-needle epilator was 30. This shows that the effectiveness of these two devices, according to this standard, are equivalent end that they met the standard for permanence as set by the Guild.

Introduction

The International Guild of Electrologists, Inc. have set standards by which they judge permanency of hair removal and the effectiveness Of hair removal devices. Traditional needle epilators which have existed fox aver a hundred years use galvanic current which is transmitted through a fine non-insulated needle into the hair follicle. This current sets off a chemical or electrolytic reaction in the follicle, producing sodium hydroxide, thus destroying the follicle. No-needle galvanic epilators (not to he confused with the high frequency tweeter devices) utilize the same process but apply the current via a tweezer grasping the hair which has been coated with a highly conductive treatment solution. It is the intent of this investigation to determine the effectiveness of this device as compared to the traditional needle epilator.

Materials and Methods

The International Guild of Professional Electrologists, Inc. have set the following procedures for evaluating alleged processes for permanent hair removal. This is quoted from page 3 of the document published by this organization entitled "Official Standards For the Treatment of Permanent Hair Removal":

1. The investigator must be a qualified graduate electrologist with no less than two years experience and a member in good standing of the International Guild of Professional Electrologists, Inc.
2. The electrified needle method must De a "Federal Communications Commission" approved device.
3. Subject: male o r female, between the ages oi 20 years and 30 years.
4. Test area: Anterior shin.
5. For control purposes 50 terminal hairs are to be removed within a very concentrated area, using an electrified needle; and in close proximity, 50 terminal hairs are to be removed by the test method.
6. The control and test sites are to be carefully examined weekly for 9 weeks. Hairs appearing within 14 days are to be considered anagen hair, which will be charted and not considered regrowth. Regrowth hair is hair which emanates from treated follicles.
7. After 9 weeks, results will De recorded and efficacy will be determined.

GUARANTY HAIR REMOVAL CLINICAL TRIALS
COMPARISON OF EFFECTIVENESS OF NEEDLE AND TWEEZER ELECTROLYSIS

Abstract: We compared the effectiveness of hair epilation using two electrolysis devices, a needle epilator and a tweezer epilator. The study was designed to comply with the standards set forth by a national electrologists' group. The average number of hairs that regrew with the needle epilator was 30; the average regrowth with the tweezer epilator was 20. This shows that the effectiveness of these two devices, according to this standard, are equivalent and that they meet the standard for permanence as set by this group.

Introduction:

A national electrologists' group has set standards by which one can judge permanency of hair removal and the effectiveness of hair removal devices. Traditional needle epilators which have existed for over 120 years, use galvanic current which is transmitted through a fine non-insulated needle into the hair follicle. This current produces a chemical (electrolytic) reaction in the follicle producing sodium hydroxide that dissolves the follicular tissue. Galvanic tweezer epilators (not to be confused with high frequency tweezer devices) utilize the same process but apply the negative direct current via an insulated tweezer grasping the hair which has been coated with a highly conductive treatment solution. It is the intent of this investigation to determine the effectiveness of this device as compared to the traditional needle epilator.

Materials and Methods

A national electrologists' group has suggested the following procedures for evaluating alleged processes for permanent hair removal. The following procedures were used as the basis for a blinded clinical evaluation of the efficacy of the GHR galvanic tweezer epilator:

1. The investigator must be a qualified graduate electrologist with no less than two years experience and a member in good standing of the International Guild of Professional Electrologists, Inc.
2. The electrified needle method must be a "Federal Communications Commission" approved device.
3. Subject: male or female, between the ages of 20 and 30 years.
4. Test area: anterior shin.
5. For control purposes 50 terminal hairs are to be removed within a very concentrated area, using an electrified needle and in close proximity, 50 terminal hairs are to be removed by the test method.
6. The control and test sites are to be carefully examined weekly for 9 weeks. Hair appearing within 14 days are to be considered anagen hair which will be charted and not considered regrowth. Regrowth hair is hair which emanates from treated follicles.
7. After 9 weeks, results will be recorded and efficacy determined.

Using these test procedures we treated five subjects, ranging in age from 21 to 53 years. The electrified needle device used was the Hinkel Blend Galvanic/Thermolysis machine with a needle diameter of .002 inches. The device was set at a galvanic only setting of 55. The no-needle device used was the AHRS Epilator 629. The manufacturers' instructions for treatment were followed. All procedures were done by a licensed, certified electrologist with 3 years experience.

On each of the five test subjects, two adjacent sites on the right anterior shin with fifty visible hairs each were identified and marked with a combination of permanent pigment and measurements from the ankle. For each subject, these fifty hairs were treated with the test devices.

Following these treatments, the subjects were examined weekly. After 2 weeks, all hairs visible within the site were counted and charted. After 9 weeks, the subjects were again examined and the total number of hairs counted and charted. As stated in the above protocol, the total number of hairs that regrew were considered to be those that had appeared between the 2nd and 9th week.

The following is a summary of the results obtained:

Subject	Age,race,sex	# of Regrown hairs Needle	No-needle
1	21 y.o. white female	25	30
2	30 y.o. black female	32	29
3	40 y.o. white male	24	30
4	53 y.o. white female	36	38
5	41 y.o. white female	30	22
	AVERAGE	29	30

Conclusions:

From a study of these results, it is reasonable to conclude that both of these devices achieve equivalent results in removing hair. Both of these devices appear to achieve electrolysis. They do comply with the definition set forth by the International Guild of Professional Electrologists, Inc. as being 'effective', since they both removed permanently at least 40% of the hairs on one treatment in this study.

Using these test procedures we treated five subjects, ranging in age from 21 to 53 years. The electrified needle device used was the Instantron Elite Galvanic/Thermolysis epilator with standard un-insulated needles of .002 and .003 inches diameter. The device was set at a galvanic only setting according to the tolerance of the patient, generally .1 to .2 mA. The galvanic tweezer device used was the **GHR** epilator Model B10AN220MFS, FDA medical device #A601886. The manufacturer's instruction for treatment were followed. All procedures were done by a certified electrologist with 12 years experience.

On each of the five test subjects, two adjacent sites on the right anterior shin with fifty visible hairs each were identified and marked with a combination of semi-permanent pigment (12 weeks durability) and anthropometric measurements. For each subject, each site was treated with both the needle device and the tweezer test device.

Following these treatments, the subjects were examined weekly. After two weeks, all hairs visible within the site were counted and charted. After 9 weeks, the subjects were again examined and the total number of hairs counted and charted. As stated in the above protocol, the total number of hairs that regrew were considered to be those that had appeared between the 2nd and 9th week.

The following is a summary of the results obtained:

Subject Age, Race, Sex	Number of Regrown Hairs and Percentage of Hairs Killed Needle	GHR Tweezer
21 yr old white female	27 hairs or 46%	19 hairs or 62%
30 yr old black female	35 hairs or 30%	22 hairs or 56%
40 yr old white male	23 hairs or 54%	17 hairs or 66%
53 yr old white female	36 hairs or 28%	18 hairs or 64%
41 yr old white female	30 hairs or 40%	22 hairs or 56%
Average Percent Killed:	Needle = 40%,	GHR tweezer = 60%

Conclusions:

From a study of these results, it' is reasonable to conclude that; both of these devices achieve permanent results with the tweezer device being 150% more effective **in** destroying the germinative cells of the hair follicle with a single treatment. The needle device achieved the minimum standard definition of "Permanent Hair Removal" as developed by a national electrologists' group. The tweezer device achieved more because the destructive energy created around the hair is exclusively inside the follicle. Both devices achieve a minimum of 40% permanent hair removal in one treatment in this study.

pH Analysis of Hair Removed via Electrolysis . .

I. Synopsis

A comparison was made of the pH level of the hair root on test subjects following epilation with 1) a no needle electrolysis device, 2) a needle electrolysis device, and 3)simple tweezing with no prior treatment.

II. Introduction

The reaction which occurs in electrolysis is as follows: 1) Electrical current is applied to a solution of NaCl and H_2O. 2) The current causes an ionization and subsequent rearrangement of the molecules producing NaOH. 3) In the case of electrolysis occurring in a hair follicle, the NaOH, which is a strong base with a pH >10., causes the destruction of the hair follicle. Theoretically, it should be possible to measure the pH of the hair that is epilated and discover the pH of the follicle in which the hair was growing. The pH of a normal hair is well documented to be 5.5 or well in the acidic range (<7). It stands to reason that the bulb or base af a hair epilated after treatment with an electrolysis device will have a Strongly alkaline pH if electrolysis does indeed occur in the hair follicle. The purpose of this test, then, is to determine the pH of the hair follicle, both in a control situation (simple tweezing), and with two types of electrolysis devices, a no-needle and needle device.

III. Materials and Methods

We epilated [ ] hairs each on [ ] test subjects with 1) the AHRS Epilator 628, a no-needle electrolysis device, 2)the A.R. Hinkel Co. Electro-Blend Epilator set in the galvanic only mode, and 3)simple tweezing. The hairs were chosen at random from a [ ] square of the chin. Each subject was treated according to the manufacturer's instructions.

IV. Results

The actual pH measurements for each of the subjects are listed in the following chart:

Guaranty Hair Removal Clinioal Trials
pH Analysis of' Hair Removed via Electrolysis

I. SYNOPSIS

A comparison was made of the pH level of the hair root on three test subjects following epilation with 1) a tweezer electrolysis device, 2) a needle electrolysis device, and 3) simple mechanical tweezing with no treatment.

II. INTRODUCTION

The reaction which occurs in electrolysis is as follows: 1. Direct electrical current is applied to a solution of NaCl and H2O (saline or salt water).2. The current causes a breakdown of this compound into the component parts that are subsequently rearranged into new compounds around the respective poles. This process is called ionization. Sodium hydroxide (NaOH) forms at the negative pole and hydrochloric acid (HC1) forms at the positive pole. Either compound will achieve permanent hair removal but traditionally, the negative is used in needle electrolysis because a reaction between the hydrochloric acid and the metal of the needle produces a tattoo from a metal deposit being left in the skin. 3. In the case of electrolysis occurring in a hair follicle, either a strong base (NaOH) or acid (HC1) will cause the destruction of the hair follicle. Measurement of the pH of the epilated hair's bulb will validate the creation of either a base or acid due to the action of the current on the hair follicle when applied either through a needle as in traditional electrolysis or through the hair as with the GHR galvanic tweezer technique. The normal pH of hair is well documented to be in the slightly acidic range (4.5 to 5.5) [1,2]. The normal body pH is in the neutral (6.5 to 7.5) range so the pH of the epilated bulbs would reflect the pH of the hair follicle at the time of epilation. Human tissue does not survive a pH >(greater than) 10 or <(less than) 4. Therefore, the presence of a pH within these parameters is evidential of destruction to the follicle sufficient to prevent its regeneration. The purpose of this test is to determine the pH of the hair follicle in a control situation (mechanical tweezing) and with two types of electrolysis devices, the needle and tweezer.

III. MATERIALS AND METHODS

We epilated 6 hairs from each of three test subjects. Each subject was treated with 1) the GHR galvanic tweezer device, 2) the Instantron Elite needle epilator set in galvanic only, and 3) simple tweezing of untreated hairs. The hairs were chosen at random from the chin area on each of the subjects. Each subject was treated according to the manufacturer's instructions. Subject 1 was a 33 year old white male, subject 2 was a 26 year old white female and subject 3 was a 42 year old white female. After treatment and epilation, the pH of the hair root was measured using Baxter Scientific Products pH indicator strips for 7.0 - 14.0. These strips effectively measure the pH of basic (alkaline) substances. No change in reagent color indicate a pH of 7 or less. Because the intent of this analysis is to measure bases, the true pH of tweezed hair (4.5 to 5.5) was not quantified. Therefore, anything that registered no change in reagent color was recorded as a pH of 7. The strips were moistened with distilled water. As a control test for test strip accuracy, the pH of 1 molar NaOH was tested and found to have a pH of 14.

IV. RESULTS

The pH measurements for each of the subjects' 6 hairs are listed in the following chart.

	No-needle device			Needle device			Tweezing only		
Subject #	1	2	3	1	2	3	1	2	3
HAIR 1	11	12	13	10	11	12	7	7	7
HAIR 2	11	11	9	12	7	7	7	7	7
HAIR 3	10	7	12	13	10	11	7	7	7
HAIR 4	13	7	12	12	11	12	7	7	7
HAIR 5	12	11	12	11	12	11	7	7	7
HAIR 6	12	12	12	11	12	11	7	7	7
AVERAGE	11.5	10	12	11.5	10.5	11	7	7	7

The average pH for both the no-needle device and the needle device were 11, with a range for both machines of 7 to 13. the pH of the tweezed hairs were all 7.

V. Discussion

The average pH obtained with both of these devices were well above the normal hair pH of 5-5.5, as wall as the normal interstitial pH of 7.2-7.4. The hairs which had a pH of 7 or less can be attributed to the fact that the electrolytic reaction can only take place when the hairs are in their anagen stage[2]. These hairs were either in the catagen or most likely the telogen stage of hair growth.

From these measurements, it is reasonable to conclude that the electrolysis reaction, described in the introduction, is occurring with both of these devices. It is also reasonable to conclude that these devices produce an equal amount of NaOH as a product of electrolysis.

References:

1. Fitzpatrick, Thomas B. et al: Dermatology in General Medicine, Third Edition, New York, McGraw-Hill, Inc. 1987.

2. Hinkel Arthur Ralph, Lind Richard W.: Electrolysis, Thermolysis and the Blend: The Principles and Practice of Permanent Hair Removal. Los Angeles, CA; Arroway, 1968.

	No-needle device			Needle device			Tweezing only		
Subject #	1	2	3	1	2	3	1	2	3
HAIR 1	11	12	13	10	11	12	7	7	7
HAIR 2	11	11	9	12	7	7	7	7	7
HAIR 3	10	7	12	13	10	11	7	7	7
HAIR 4	13	7	12	12	11	12	7	7	7
HAIR 5	12	11	12	11	12	11	7	7	7
HAIR 6	12	12	12	11	12	11	7	7	7
AVERAGE	11.5	10	12	11.5	10.5	10.5	7	7	7

The average pH for both the tweezer device and the needle device is 11, with a range for both devices of 7 to 13. The average pH for all hairs treated with the needle is 10.89 and for the tweezer device is 11.07. A higher average pH (18%) was achieved with the tweezer device treated hairs. The pH of the tweezed hairs were all 7 indicating no base reaction inside untreated follicles.

V. Discussion

The average pH obtained with both of these devices were well above the normal hair pH of 4.5 to 5.5 as well as the normal interstitial pH of 7.2 to 7.4[3]. The hairs that showed no reaction to the reagent strips can be attributed to the fact that the electrolytic reaction can only take place when a hair follicle exists, primarily in the anagen and catagen phases4. These hairs were most likely in the telogen phase of the hair growth cycle when no follicle is present.

From these measurements, it is reasonable to conclude that the electrolysis reaction, described in the introduction, is occurring with both of these devices. It is also reasonable to conclude that these devices produce an equal amount of NaOH as a product of electrolysis.

References

1.Fitzpatrick, Thomas B., et al;, Dermatology in General Medicine, Third edition, New York, McGraw-Hill, Inc., 1987.
2.Powitt. A.H.. Hair Structure and Chemistry Simplified, New York, Delmar Publishers, Inc., 1990.
3.Montagna, William and Ellis, Richard A., The Biology of Hair Growth, New York, Academic Press, Inc., 1958.
4.Hinkel, Arthur Ralph, and Lind, Richard W., Electrolysis, Thermolysis And The Blend: The Principles and Practice of Permanent Hair Removal, Los Angeles, Arroway, 1968.

Conclusion

For over a decade, Hubert Lee Cole has shown a pattern of false and misleading activity in promoting epilators, first as American Hair Removal Systems, later as International Hair Removal Systems, and most recently as Rejuvenu International Limited.

As I have noted in other correspondence with FDA, in Docket K8925 14, Mr. Cole led FDA to believe that William Chandler, also known as Mark H. Chandler, (the "expert" Mr. Cole claims conducted these disputed tests) was a dermatologist, when in fact he is not. I also noted that Shirley Singleton, claimed by Mr. Cole to be the "licensed, certified electrologist and registered nurse," who supposedly performed the testing, did not appear to exist according to North Carolina registration records for these occupations.

In addition to the submission of false and misleading information in Docket K892514, Mr. Cole has been cited for numerous subsequent violations of FDA regulations. Mr. Cole has ignored repeated requests by FDA to cease making violative promotional claims for the epilators he sells. The most recent was sent by Patricia Jahnes on 2 April 2001. As of the date of this petition, Mr. Cole continues to promote his transcutaneous patch epilators as permanent despite numerous attempts by FDA to get him to stop.

FDA Final Rule in Docket 97N-0199 stated that tweezer-type epilators had not proven they were permanent:

> FDA agrees with the comments that there is no body of significant information establishing the effectiveness of the device to permanently remove hair.. . FDA acknowledges that there is no statistically significant scientific data available at this time to support promotional claims of permanent or long-term removal of hair through use of the device.

Since the tweezer reclassification, FDA has allowed AHRS to continue to claim permanent hair removal, but in light of the disputed data in the **AHRS** submission, this petition requests this clearance be reviewed.

This is an opportunity for FDA to clarify the confusion in the consumer marketplace that began with the original clearance for this electric tweezer as permanent. Letters sent by FDA have not been enough to get Mr. Cole to cease promoting his epilators with false and misleading claims. Mr. Cole and his accomplices will continue to deceive consumers until decisive steps are taken.

In light of evidence that Mr. Cole submitted false and misleading data, this petition requests FDA take the decisive step of rescinding this clearance as permanent and consider taking appropriate punitive action.

Passages from FDA clearance based on identical AHRS/GHR data

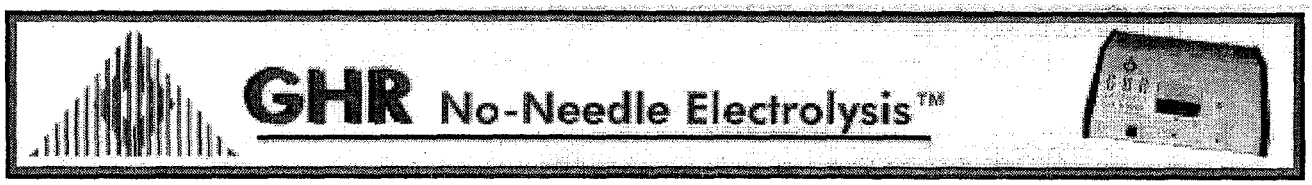
FDA clearance in Docket K892514

Relevant passages from evaluation by FDA reviewer Paul Tilton:

> Because of the technological difference between the 2 device types, the question of device effectiveness is raised. To demonstrate the equivalency of the AHRS Epilator to needle-type electrolysis devices, AHRS submitted results of several studies. The first study was conducted by Mark Chandler, M.D., a dermatologist contracted by AHRS. It involved a comparison of pH level to the hair root on 3 test subjects following epilation with either 1) the AHRS Epilator; 2) a galvanic needle-type epilator; and 3) manual tweezing with no prior treatment. Six hairs were removed from each test subject using the 3 different methods. Results demonstrated that the average pH of both the hair roots removed by the AHRS device and the galvanic needle-type epilator were pH 11 (with a range for both devices of pH 7 to pH13), while the pH of the tweezed hairs were all pH 7 or less. The pH of the conductive gel is pH 5.5. From this data, Dr. Chandler concluded that the electrolysis reaction is occurring with both of these devices and that these devices produce an equal amount of NaOH is a product of electrolysis.
>
> In addition, a controlled clinical trial was conducted by Dr. Chandler, which compared the effectiveness of hair epilation using a galvanic needle-type epilator and the AHRS Epilator 629. The study followed the standard procedures established by the International Guild of Professional Electrologists, Inc. for evaluating the effectiveness of epilators for permanent hair removal. FDA has not established its own guideline for testing for effectiveness in permanent hair removal, not defined "permanence." Five test subjects (4 females and 1 male, ranging in age from 21 to 53 years) were treated, using the Guild's test procedures. The procedure involves removing 50 hairs from the subject's anterior shin within a concentrated area, using the needle device (control) and doing the same in an area in close proximity, using the test method. Test and control sites are examined weekly for 9 weeks. Hair appearing within 14 days were considered anagen hair (which were charted and not considered regrowth). Regrowth hair is hair which emanates from treated follicles. After 9 weeks, results were recorded. From the study results, Dr. Chandler concluded that both the devices achieved equivalent results in removing hair and both complied with the definition set forth by the International Guild of Professional Electrologists, Inc. as being effective, since they both removed permanently at least 40 percent of the hairs on one treatment in this study.
>
> I believe that it is reasonable to conclude that results of the testing, as described above, demonstrate that the AHRS epilator 629 is substantially equivalent to predicate galvanic needle-type epilators, in terms of effectiveness. Therefore, I recommend that the device be deemed substantially equivalent to predicate galvanic needle-type epilators.
>
> The AHRS Epilator 629 is an electrolysis device that is intended to destroy the roots of unwanted hair with an electrical current for the purpose of permanent hair removal. It is accomplished by the destruction of the dermal papilla and the surrounding germative cells in the lower portion of the hair follicle.

GHR data marked "Copyright ©1987"

Sources: http://www.hairfree.com/studies.htm
http://www.consumerbeware.com/ghr_studies.htm



Guaranty Hair Removal Clinical Trials
Comparison of the Effectiveness of Needle and Tweezer Electrolysis

ABSTRACT:
We compared the effectiveness of hair epilation using two electrolysis devices, a needle epilator and a tweezer epilator. The study was designed to comply with the standards set forth by a national electrologists' group. The average number of hairs that regrew with the needle epilator was 30; the average regrowth with the tweezer epilator was 20. This shows that the effectiveness of these two devices, according to this standard, are equivalent and that they meet the standard for permanence as set by this group.

INTRODUCTION:
A national electrologists' group has set standards by which one can judge permanency of hair removal and the effectiveness of hair removal devices. Traditional needle epilators which have existed for over 120 years, use galvanic current which is transmitted through a fine non-insulated needle into the hair follicle. This current produces a chemical (electrolytic) reaction in the follicle producing sodium hydroxide that dissolves the follicular tissue. Galvanic tweezer epilators (not to be confused with high frequency tweezer devices) utilize the same process but apply the negative direct current via an insulated tweezer grasping the hair which has been coated with a highly conductive treatment solution. It is the intent of this investigation to determine the effectiveness of this device as compared to the traditional needle epilator.

MATERIALS AND METHODS:
A national electrologists' group has suggested the following procedures for evaluating alleged processes for permanent hair removal. The following procedures were used as the basis for a blinded clinical evaluation of the efficacy of the **GHR** galvanic tweezer epilator:

1. The investigator must be a qualified graduate electrologist with no less than two years experience and a member in good standing of the International Guild of Professional Electrologists, Inc.
2. The electrified needle method must be a "Federal Communications Commission" approved device.
3. Subject: male or female, between the ages of 20 and 30 years.
4. Test area: anterior shin.
5. For control purposes 50 terminal hairs are to be removed within a very concentrated area, using an electrified needle and in close proximity, 50 terminal hairs are to be removed by the test method.
6. The control and test sites are to be carefully examined weekly for 9 weeks. Hair appearing within 14 days are to be considered anagen hair which will be charted and not considered regrowth. Regrowth hair is hair which emanates from treated follicles.
7. After 9 weeks, results will be recorded and efficacy determined.

Using these test procedures we treated five subjects, ranging in age from 21 to 53 years. The electrified needle device used was the Instantron Elite Galvanic/Thermolysis epilator with standard un-insulated needles of .002 and .003 inches diameter. The device was set at a galvanic only setting according to the tolerance of the patient, generally .1 to .2 mA.

The galvanic tweezer device used was the **GHR** epilator Model B10AN220MFS, FDA medical device #A601886. The manufacturer's instruction for treatment were followed. All procedures were done by a certified electrologist with 12 years experience.

On each of the five test subjects, two adjacent sites on the right anterior shin with fifty visible hairs each were identified and marked with a combination of semi-permanent pigment (12 weeks durability) and anthropometric measurements. For each subject, each site was treated with both the needle device and the tweezer test device.

Following these treatments, the subjects were examined weekly. After two weeks, all hairs visible within the site were counted and charted. After 9 weeks, the subjects were again examined and the total number of hairs counted and charted. As stated in the above protocol, the total number of hairs that regrew were considered to be those that had appeared between the 2nd and 9th week.

The following is a summary of the results obtained:

Subject Age, Race, Sex	Number of Regrown Hairs and Percentage of Hairs Killed	
	Needle	GHR Tweezer

21 yr old white female	27 hairs or 46%	**19 hairs or 62%**
30 yr old black female	35 hairs or 30%	**22 hairs or 56%**
40 yr old white male	23 hairs or 54%	**17 hairs or 66%**
53 yr old white female	36 hairs or 28%	**18 hairs or 64%**
41 yr old white female	30 hairs or 40%	**22 hairs or 56%**

Average Percent Killed: Needle = 40%, GHR tweezer = 60%

CONCLUSIONS:
From a study of these results, it is reasonable to conclude that both of these devices achieve permanent results with the tweezer device being 150% more effective in destroying the germinative cells of the hair follicle with a single treatment. The needle device achieved the minimum standard definition of "Permanent Hair Removal" as developed by a national electrologists' group.

The tweezer device achieved more because the destructive energy created around the hair is exclusively inside the follicle. Both devices achieve a minimum of 40% permanent hair removal in one treatment in this study.

pH Analysis of Hair Removed via Electrolysis

1. SYNOPSIS
A comparison was made of the pH level of the hair root on three test subjects following epilation with 1) a tweezer electrolysis device, 2) a needle electrolysis device, and 3) simple mechanical tweezing with no treatment.

II. INTRODUCTION
The reaction which occurs in electrolysis is as follows:

1. Direct electrical current is applied to a solution of NaCl and H_2O (saline or salt water).

2. The current causes a breakdown of this compound into the component parts that are subsequently rearranged into new compounds around the respective poles. This process is called **ionization.** Sodium hydroxide (NaOH) forms at the negative pole and hydrochloric acid (HCl) forms at the positive pole. Either compound will achieve permanent hair removal but traditionally, the negative is used in needle electrolysis because a reaction between the hydrochloric acid and the metal of the needle produces a tattoo from a metal deposit being left in the skin.

3. In the case of electrolysis occurring in a hair follicle, either a strong base (NaOH) or acid (HCl) will cause the destruction of the hair follicle. Measurement of the pH of the epilated hair's bulb will validate the creation of either a base or acid due to the action of the current on the hair follicle when applied either through a needle as in traditional electrolysis or through the hair as with the **GHR** galvanic tweezer technique.

The normal pH of hair is well documented to be in the slightly acidic range (4.5 to 5.5) [1,2]. The normal body pH is in the neutral (6.5 to 7.5) range so the pH of the epilated bulbs would reflect the pH of the hair follicle at the time of epilation. Human tissue does not survive a pH >(greater than) 10 or <(less than) 4. Therefore, the presence of a pH within these parameters is evidential of destruction to the follicle sufficient to prevent its regeneration.

The purpose of this test is to determine the pH of the hair follicle in a control situation (mechanical tweezing) and with two types of electrolysis devices, the needle and tweezer.

111. MATERIALS AND METHODS
We epilated 6 hairs from each of three test subjects. Each subject was treated with 1) the GHR galvanic tweezer device, 2) the Instantron Elite needle epilator set in galvanic only, and 3) simple tweezing of untreated hairs. The hairs were chosen at random from the chin area on each of the subjects. Each subject was treated according to the manufacturer's instructions. Subject 1 was a 33 year old white male, subject 2 was a 26 year old white female and subject 3 was a 42 year old white female.

After treatment and epilation, the pH of the hair root was measured using Baxter Scientific Products pH indicator strips for 7.0 - 14.0. These strips effectively measure the pH of basic (alkaline) substances. No change in reagent color indicate a pH of 7 or less. Because the intent of this analysis is to measure bases, the true pH of tweezed hair (4.5 to 5.5) was not quantified. Therefore, anything that registered no change in reagent color was recorded as a pH of 7. The strips were moistened with distilled water. As a control test for test strip accuracy, the pH of 1 molar NaOH was tested and found to have a pH of 14.

IV. RESULTS

The pH measurements for each of the subjects' 6 hairs are listed in the following chart.

Device	Subject Number	Hair #1	Hair #2	Hair #3	Hair #4	Hair #5	Hair #6	Average
Tweezer Only	1	7	7	7	7	7	7	7
	2	7	7	7	7	7	7	7
	3	7	7	7	7	7	7	7
Needle Device	1	10	12	13	12	11	11	11.5
	2	11	7	10	11	12	12	10.5
	3	12	7	11	12	11	11	11
Tweezer Device	1	11	11	10	13	12	12	11.5
	2	12	11	7	7	11	12	10
	3	13	9	12	12	12	12	12

The average pH for both the tweezer device and the needle device is 11, with a range for both devices of 7 to 13. The average pH for all hairs treated with the needle is 10.89 and for the tweezer device is 11.07. A higher average pH (18%) was achieved with the tweezer device treated hairs. The pH of the tweezed hairs were all 7 indicating no base reaction inside untreated follicles.

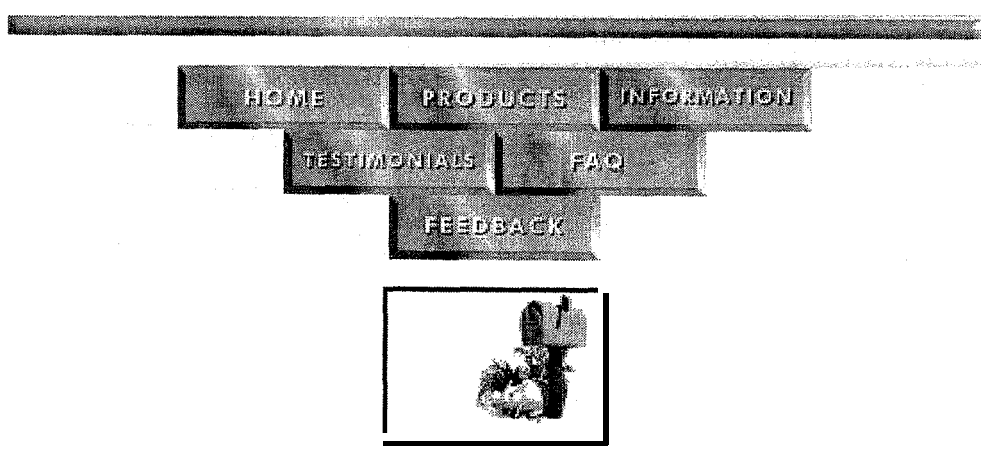
V. DISCUSSION

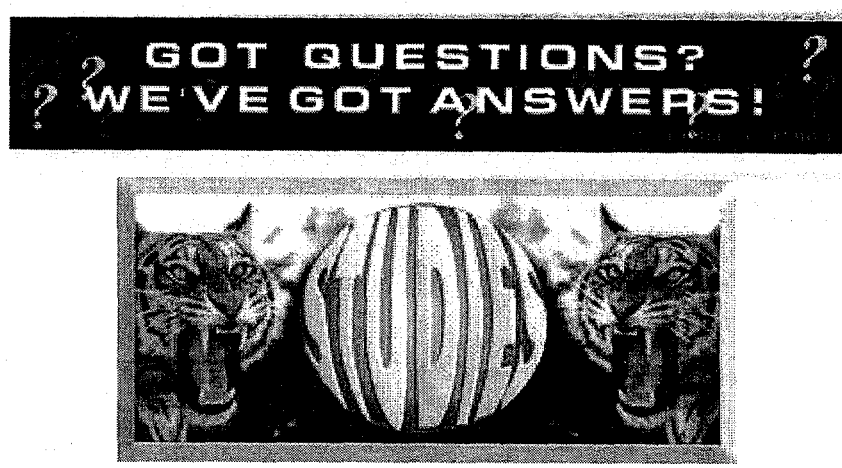
The average pH obtained with both of these devices were well above the normal hair pH of 4.5 to 5.5 as well as the normal interstitial pH of 7.2 to 7.4[3]. The hairs that showed no reaction to the reagent strips can be attributed to the fact that the electrolytic reaction can only take place when a hair follicle exists, primarily in the anagen and catagen phases[4]. These hairs were most likely in the telogen phase of the hair growth cycle when no follicle is present.

From these measurements, it is reasonable to conclude that the electrolysis reaction, described in the introduction, is occurring with both of these devices. It is also reasonable to conclude that these devices produce an equal amount of NaOH as a product of electrolysis.

REFERENCES:

1. Fitzpatrick, Thomas B., *et* al, *Dermatology in General Medicine,* Third edition, New York, McGraw-Hill, Inc., 1987.
2. Powitt, A.H., *Hair Structure and Chemistry Simplified,* New York, Delmar Publishers, Inc., 1990.
3. Montagna, William and Ellis, Richard A., *The Biology of Hair Growth,* New York, Academic Press, Inc., 1958.
4. Hinkel, Arthur Ralph, and Lind, Richard W., *Electrolysis, Thermolysis And The Blend: The Principles and Practice of Permanent Hair Removal,* Los Angeles, Arroway, 1968.





Guaranty Hair Removal Clinical Trials
Comparison of the Effectiveness of Needle and Tweezer Electrolysis

ABSTRACT:
We compared the effectiveness of hair epilation using two electrolysis devices, a needle epilator and a tweezer epilator. The study was designed to comply with the standards set forth by a national electrologists' group. The average number of hairs that regrew with the needle epilator was 30; the average regrowth with the tweezer epilator was 20. This shows that the effectiveness of these two devices, according to this standard, are equivalent and that they meet the standard for permanence as set by this group.

INTRODUCTION:
A national electrologists' group has set standards by which one can judge permanency of hair removal and the effectiveness of hair removal devices. Traditional needle epilators which have existed for over 120 years, use galvanic current which is transmitted through a fine non-insulated needle into the hair follicle. This current produces a chemical (electrolytic) reaction in the follicle producing sodium hydroxide that dissolves the follicular tissue. Galvanic tweezer epilators (not to be confused with high frequency tweezer devices) utilize the same process but apply the negative direct current via an insulated tweezer grasping the hair which has been coated with a highly conductive treatment solution. It is the intent of this investigation to determine the effectiveness of this device as compared to the traditional needle epilator.

MATERXALS AND METHODS:
A national electrologists' group has suggested the following procedures for evaluating alleged processes for permanent hair removal. The following procedures were used as the basis for a blinded clinical evaluation of the efficacy of the **GHR** galvanic tweezer epilator:

1. The investigator must be a qualified graduate electrologist with no less than two years experience and a member in good standing of the International Guild of Professional Electrologists, Inc.
2. The electrified needle method must be a "Federal Communications Commission" approved device.
3. Subject: male or female, between the ages of 20 and 30 years,
4. Test area: anterior shin.
5. For control purposes 50 terminal hairs are to be removed within a very concentrated area, using an electrified needle and in close proximity, 50 terminal hairs are to be removed by the test method.
6. The control and test sites are to be carefully examined weekly for 9 weeks. Hair appearing within 14 days are to be considered anagen hair which will be charted and not considered regrowth. Regrowth hair is hair which emanates from treated follicles.
7. After 9 weeks, results will be recorded and efficacy determined.

Using these test procedures we treated five subjects, ranging in age from 21 to 53 years. The electrified needle device used was the Instantron Elite Galvanic/Thermolysis epilator with standard un-insulated needles of .002 and .003 inches diameter. The device was set at a galvanic only setting according to the tolerance of the patient, generally .1 to .2 mA.

The galvanic tweezer device used was the **GHR** epilator Model B10AN220MFS, FDA medical device #A601886. The manufacturer's instruction for treatment were foilowed. All procedures were done by a certified electrologist with 12 years experience.

On each of the five test subjects, two adjacent sites on the right anterior shin with fifty visible hairs each were identified and marked with a combination of semi-permanent pigment (12 weeks durability) and anthropometric measurements. For each subject, each site was treated with both the needle device and the tweezer test device.

Following these treatments, the subjects were examined weekly. After two weeks, all hairs visible within the site were counted and charted. After 9 weeks, the subjects were again examined and the total number of hairs counted and charted. As stated in the above protocol, the total number of hairs that regrew were considered to be those that had appeared between the 2nd and 9th week.

The following is a summary of the results obtained:

Subject Age, Race, Sex	Number of Regrown Hairs and Percentage of Hairs Killed	
	Needle	GHR Tweezer
21 yr old white female	27 hairs or 46%	**19 hairs or 62%**
30 yr old black female	35 hairs or 30%	**22 hairs or 56%**
40 yr old white male	23 hairs or 54%	**17 hairs or 66%**
53 yr old white female	36 hairs or 28%	**18 hairs or 64%**
41 yr old white female	30 hairs or 40%	**22 hairs or 56%**

Average Percent Killed: Needle = 40%, GHR tweezer = 60%

CONCLUSIONS:
From a study of these results, it is reasonable to conclude that both of these devices achieve permanent results with the tweezer device being 150% more effective in destroying the germinative cells of the hair follicle with a single treatment. The needle device achieved the minimum standard definition of "Permanent Hair Removal" as developed by a national electrologists' group.

The tweezer device achieved more because the destructive energy created around the hair is exclusively inside the follicle. Both devices achieve a minimum of 40% permanent hair removal in one treatment in this study.

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4. Hinkel, Arthur Ralph, and Lind, Richard W., Electrolysis, *Thermolysis And The Blend: The Principles and Practice of Permanent Hab Removal,* Los Angeles, Arroway, 1968.

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