A RANDOMIZED, DOUBLE BLIND STUDY IN 64 SUBJECTS TO EVALUATE THE EFFICACY OF ONE TEST ARTICLE TO CONTROL BREATH ODOUR 13 HOURS AFTER A SINGLE USE COMPARED TO AN UNTREATED CONTROL GROUP AND A POSITIVE CONTROL GROUP USING HEDONIC ASSESSMENTS.

Prepared for:

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A RANDOMIZED, DOUBLE BLIND STUDY IN 64 SUBJECTS TO EVALUATE THE EFFICACY OF ONE TEST ARTICLE TO CONTROL BREATH ODOUR 13 HOURS AFTER A SINGLE USE COMPARED TO AN UNTREATED CONTROL GROUP AND A POSITIVE CONTROL GROUP USING HEDONIC ASSESSMENTS.

PRINCETON CONSUMER RESEARCH REPORT NO: KATODR1

I declare that the following report constitutes a true and faithful account of the procedures adopted and the results obtained in the performance of this study. The aspects of the study conducted by Princeton Consumer Research were performed, where relevant, in accordance with the principles of Good Clinical Research Practice.

Danny McCamlie
(Principal Investigator)

.....

Date 26th Nov 14

Bryan Baker
(Project Manager)

.....

Date 26th Nov 2014

QUALITY ASSURANCE STATEMENT

This report has been audited and is considered to be an accurate description of the methods used and an accurate presentation of the data obtained during the conduct of the study.

Danielle Smith
(Quality Assurance Manager)

.....

Date 26/11/14

CONTENTS

SUMMARY

1. This was a randomised, double-blind within subject comparison study conducted in 64 healthy volunteers to evaluate the efficacy of one test article to control breath odour, 13 hours after a single use compared to an untreated control group and a positive control group using hedonic assessments.

2. The test articles were applied once on day 1 of the study.

3. Four judges conducted hedonic assessments in a blinded fashion, pre-product application, 1 hour and 13 hours post product application.

4. Individual scores, mean scores and standard deviations for each assessment point are presented in this report for the 64 subjects who completed the study for each of the four judges.

5. There was no statistically significant difference for the pre-treatment assessments between the test groups for any of the judges or between judges ($p>0.05$) so the study can be considered valid. Both the Test Article and Positive Control showed a highly statistically significant difference to the untreated baseline sites ($p<0.005$) in all assessments. All judges were statistically similar at all-time points and sites ($p>0.05$) and so assessments can be considered as accurate.

6. It can be concluded that for the test articles the claims of "breath freshening" and "freshens breath for over 12 hours" are valid.

KEY STUDY PERSONNEL AND RESPONSIBILITIES

Key personnel	General responsibilities
Principal Investigator (PI) Danny McCamlie Princeton Consumer Research Harbour House 23 Chandlers Quay Maldon Essex CM9 4LF United Kingdom Tel: 01621 859230 Fax: 01621 851537	The Principal Investigator (PI) was responsible for ensuring sufficient resources were available to conduct the study according to Good Clinical Practice (GCP), for reporting any serious adverse events to the Sponsor, for the study design, compiling the results and writing the clinical report.
Project Manager (PM) Bryan Baker Princeton Consumer Research Harbour House 23 Chandlers Quay Maldon Essex CM9 4LF United Kingdom Tel: 01621 859230 Fax: 01621 851537	The Project Manager (PM) was involved with the study design, compiling the results and writing the clinical report.
Project Supervisor (PS) Barrie Drewitt Princeton Consumer Research Princeton Forrestal Center 307 College Rd East Princeton, NJ, 08540 e-mail: barriedrewitt@princetonconsumer.com	The Project Supervisor (PS) was responsible for the conduct of the study on a daily basis.
Project Co-ordinator (PC) Mark Fiala Dr. Harold Katz LLC 750 N. Highland Ave. LA, CA 90038 e-mail: mark@drkatz.com	The Project Co-ordinator (PC) will be the primary point of contact on behalf of the Sponsor of this project and will represent the Sponsor (Dr. Harold Katz LLC) of this study.

1. INTRODUCTION AND OBJECTIVE

The objective of this study was to determine the efficacy of a toothpaste to mask breath malodour for up to and including 13 hours following a standard usage in comparison to an untreated and positive control group using hedonic assessments by a panel of qualified odour judges.

2. STUDY DESIGN

A randomised, blinded study lasting approximately 11 days, including the washout period with one treatment site per subject; the subject's breath designated as a treatment site. The pre-treatment (washout) phase will consist of at least 10 days and the treatment phase will consist of 1 days.

3. STUDY SCHEDULE

Study Day / Stage	Day -10 to Day -1	Day 1, 0 Hour	Day 1, 1 Hour	Day 1, 13 Hour
Subject Enrollment	√			
Washout	√	√	√	√
Supervised Cleaning	√	√	√	√
Malodor Assessments		√	√	√

4. SELECTION OF SUBJECTS

4.1 Screening

Sixty four subjects were recruited from the general area surrounding the clinical site in order to enrol fifty two subjects (three of which were consensus subjects) for enrolment into the treatment phase of the study.

Prior to the study treatment initiation all prospective subjects will be screened for eligibility.

4.2 Inclusion criteria

4.2.1 Subject is aged 18-65, inclusive.

4.2.2 Agrees to NOT take antihistamines or medications with sedative affect throughout the study.

4.2.3 Does NOT have allergies to the ingredients of soaps, detergents, perfumes, cosmetics, dentifrice, oral care, skin care, or hair care products.

4.2.4 Does NOT have or had active psoriasis, eczema on any portion of their body.

4.2.5 Has NOT been diagnosed or treated for cancer in the last 5 years.

4.2.6 Has NOT taken for a chronic condition, or have taken in three days prior to the Baseline visit, any anti-inflammatory (except 81 mg-ASA per day), immunosuppressant or antihistamine.

4.2.7 Is NOT a diabetic.

4.2.8 Does NOT have any of the following condition(s): heart disease, hypertension, kidney disease, significant respiratory disease or epilepsy.

4.2.9 Be willing to refrain from brushing their teeth and using mouthwash etc on the active days of the study with the exception of articles that will be provided to them.

4.2.10 Subject has NO history of any significant immunologic or infectious disease (e.g. hepatitis, tuberculosis, positive HIV or AIDS, lupus, rheumatoid arthritis) which could place the subject at risk or interfere with the accuracy of the study results.

4.2.11 Has NOT gone swimming, used a hot tub or sat in chlorinated water within 48 hours of Baseline and is willing to avoid swimming and hot tubs during the study.

4.2.12 HAS an Average (from 4 expert odour judges) odour score of ≥ 4.0 on a 0 to 10 point scale.

4.2.13 Is NOT an employee of the Sponsor Company or CRO.

4.2.14 Is NOT taking any other medication that, in the opinion of the Investigator is likely to affect their response to treatment.

4.2.15 Has no other medical condition or factor the Investigator or their duly assigned representative believes may affect the ability of the subject to complete the study or the interpretation of the results.

4.3 Exclusion Criteria

4.3.1 Is taking for a chronic condition any anti-inflammatory (except 81 mg-ASA per day), immunosuppressant, antihistamine, or sedative medications (i.e. containing antihistamines like Tylenol pm, Nyquil, etc.).

4.3.2 Has had within 6 weeks of the study start date, or currently has, orthodontic appliances, more then once incisor with a prothestic crown or veneer, tumours of soft or hard oral tissue, moderate or advanced periodontal disease or greater than 4 caries lesions.

4.3.3 Has allergies to the ingredients of soaps, detergents, perfumes, cosmetics, anti-perspirants, deodorants, skin or hair care products, or has sensitive skin.

4.3.4 Has or has had active eczema or psoriasis on any portion of their body.

4.3.5 Has been diagnosed or treated for cancer in the past 5 years.

4.3.6 Is using or has used any systemic antibiotics within the last 2 weeks.

4.3.7 Is a diabetic

4.3.8 Has the following condition(s): heart disease, hypertension, kidney disease, significant respiratory disease, or epilepsy.

4.3.9 Has an immunologic or infectious disease (e.g. hepatitis, tuberculosis, HIV or AIDS, lupus, rheumatoid arthritis) which could place the subject at risk or interfere with the accuracy of the study results.

4.3.10 Is an employee of the Sponsor Company or CRO.

4.3.11 Is taking any other medication that, in the opinion of the Investigator is likely to affect their response to treatment.

4.3.12 Any other condition or factor the Investigator or their duly assigned representative believes may affect the ability of the subject to complete the study or the interpretation of the results.

TEST ARTICLES

To the best of the Sponsor's knowledge, the test articles did not contain antibiotics, antiseptics, steroids, hormones, or any other substances at levels of concentration requiring label declaration by the relevant regulatory authorities and were formulated and tested to comply with applicable regulations. Based on the information available, Princeton Consumer Research considered the test articles to be safe for use in man.

The following test articles were supplied by the Sponsor labelled as follows:

1. Article 197-75B
2. Positive Control (COLGATE TOTAL)

All of the test articles were used as supplied by the Sponsor. The Sponsor provided ingredient listings for the test articles (see Appendix 4). A third group were included that shall remain untreated.

It was the responsibility of the Sponsor to determine, for each batch of test articles, the identity, strength, purity, composition and other characteristics which appropriately define the test articles, before their use in the study. The determination of their stability and documentation of methods of synthesis or derivation were also the Sponsor's responsibility.

After the use of the test articles, a reserve sample of each article were stored by Princeton Consumer Research under appropriate conditions.

After an archive sample was been taken, all remaining test articles were disposed of 28 days after the completion of the study, unless requested otherwise by the Sponsor

Packaging, Labelling, and Shipping of Test Products

The Sponsor sent all test products directly to the clinical facility prior to the start of the study in compliance with current Good Manufacturing Practices. The quantity of all study material shipped to the clinical facility was documented by the CRO.

It was the responsibility of the Sponsor that test articles met all necessary transport regulations, particularly those regulations involving the carriage of hazardous goods and the import/export of goods or equipment, and that any costs including tax/duty were fully met by the Sponsor prior to receipt of test articles at Princeton Consumer Research. No liability with regard to safe receipt or costs involved in the carriage of goods or equipment to any Princeton Consumer Research site was accepted

METHOD

Pre-conditioning (Washout) Procedure

Upon arrival at the clinical site perspective subjects were consented (Appendix 1). Each subject was then given a soft bristle toothbrush and a sample of Colgate Total to be used during the pre-conditioning phase of the study, twice daily for a period of 2 minutes following their usual brushing action. Subjects were not permitted to use any other products in the mouth such as floss, mouthwash, breath mints etc.

During the entire pre-conditioning period subjects were instructed to stop using their usual toothpaste and oral care regime and were given instructions to take home with them for reference.

Day -1:

Subjects were instructed not to clean their teeth or eat at home before coming to the clinical site. Subjects were queried about whether they had been ill or if they had taken any new medications since their last visit and new information was recorded. The prospective subjects were then assessed for odour and the first sixty-four subjects to qualify 4.0 or greater were enrolled into the study (see Appendix 4). Forty-nine subjects were considered test subjects and three subjects were considered the consensus subjects.

Day 1:

Subjects were instructed not to brush their teeth or use mouth wash before coming to the clinical site and not to use any products with fragrance on their face/hair and follow all written instructions they were given. Upon arrival at the clinical site Subjects were queried about whether they had been ill or if they had taken any new medications since their last visit and new information was recorded. The prospective subjects were then assessed for odour and the first sixty four subjects to qualify 4.0 or greater (AVERAGE OF 4 JUDGES) were enrolled into the study (see Appendix 4). Sixty subjects were considered test subjects and three subjects were considered the consensus subjects. Any remaining subjects were excused from the study.

Twenty subjects were assigned to each of three time slots for Day 1; representing the 3- cohorts. Each cohort of twenty subjects was treated with the same product for the study. Subjects were dosed on Day 1 Baseline at a time relevant to their cohort. The odour judges evaluated the consensus subject for each cohort followed by the 20-subject cohort, which were treated with the same product.

Next, the qualified subjects were instructed to use the product for their group under supervised conditions (see below in Section 8.4). Subjects were given a timer set for 2 minutes and they were instructed to brush using their usual action until the timer sounded before wiping their mouths. Subjects were only able to brush their teeth at the clinical site that morning under supervision.

Following usage subjects were re-evaluated within 1 hour of use ± 10 minutes for odour. The consensus subject for the cohort was evaluated and discussed first. Subjects were then instructed not to use any products in their mouth for the following 13 hours.

13 Hours ± 15 minutes subjects then returned to the test centre for final evaluations. Following assessment subjects were exited from the study and compensated for their time and inconvenience.

Supervised Use Procedure:

Subjects were provided with a standard soft bristle toothbrush pre-loaded with 0.2ml ± 0.05ml for use. Each subject was instructed to brush following his or her usual action for 2 minutes. Following the 2 minute period subjects were instructed to spit and to wipe clean their mouth area on dry paper towelling provided by the supervisor. Subjects were not permitted to rinse their mouths.

Subjects in the Negative Control group (Untreated) were not provided with any product and the refrained from any cleaning of their teeth on the morning of the study day.

Treatment Application Procedure

Treatment Products:

Material/Product/Code	Dose	Apply Frequency
Test Article (197-75B)	0.2ml	Once
Positive Control (Colgate)	0.2ml	Once
Negative Control (Untreated)	-	-

ODOUR JUDGE IDENTIFICATION

The odour judges were assigned numbers #1 - #4 that they maintained through the study for entering their odour data.

ADVERSE EVENTS

An adverse event was anything untoward which happened to a subject during a study, whether or not it was related to the administration of the test articles.

An adverse reaction to the test articles was an adverse event occurring after the administration of the test articles which may have been causally related to the test articles.

Classification

An adverse event would have been NON-SERIOUS (sub-classified as Mild, Moderate or Severe) unless it fell into one or more of the following categories when it would be classified as SERIOUS.

The event:

- resulted in death.
- was life threatening.
- required in-patient hospitalisation or prolongation of existing hospitalisation.
- resulted in persistent or significant disability /incapacity.
- was a congenital anomaly/birth defect.

Every adverse event must be recorded and then classified as Serious or Non-Serious.

Maximum intensity of NON-SERIOUS adverse events would have been assigned to one of the following categories:

Mild: For example, an adverse event which was easily tolerated by the subject, causing minimal discomfort and not interfering with everyday activities.

Moderate: For example, an adverse event which was sufficiently discomforting to interfere with normal everyday activities.

Severe: For example, an adverse event which prevented normal everyday activities.

Reporting of adverse events

In the event of a SERIOUS adverse event, the type, onset, severity, duration and outcome would have been recorded on a Serious Adverse Event Form and the Sponsor would have been notified within one working day, with a written report following within three working days. The significance of the event would have been discussed between the Principal Investigator and the Sponsor, with the Principal Investigator reserving the right to withhold further administration pending further information and discussion. The subject's General Practitioner would have also been informed as soon as it was reasonably practicable to do so.

Non-serious events would have been reported to the Sponsor in the Clinical Report at the conclusion of the study.

Withdrawals

The participation of a subject in this study may have been discontinued for any of the following reasons:

- the subject wished to withdraw.
- if, in the opinion of the Principal Investigator/Project Manager, it was in the best interests of the subject.
- suspected adverse effects from the test articles.
- inter-current illness.
- violation of the prohibitions and restrictions (see Section 2.4).
- development of an exclusion criterion.

Subjects were free to withdraw at any time and need not have given a reason, but every reasonable attempt would have been made to ascertain such reasons. The data for any subjects who were withdrawn from the study would have been included in this report but may have been excluded from final data analysis.

Subjects would not have been followed up after their withdrawal from the study, except in the case of a Serious Adverse Event. Withdrawn subjects would not have been replaced.

PREMATURE TERMINATION OR SUSPENSION OF THE STUDY

This study may have been prematurely suspended or terminated by Princeton Consumer Research or the Sponsor. In all cases of premature suspension or termination, Princeton Consumer Research would have been promptly informed all study subjects and would have provided appropriate therapy and subject follow-up.

If the study is prematurely suspended or terminated by Princeton Consumer Research Inc without the prior agreement of the Sponsor, Princeton Consumer Research Inc will inform the Sponsor as soon as possible and will provide the Sponsor a with a detailed written explanation of the termination or suspension.

STUDY ETHICS

Amendments to protocol

Proposed changes or additions to the authorised protocol would have been subject to approval by the Principal Investigator and the Sponsor before implementation, except and insofar as Princeton Consumer Research reserved the right to make unilateral departure from the protocol to eliminate an apparent immediate hazard to subject health.

Declaration of Helsinki

The study conformed to the requirements of the 1964 Declaration of Helsinki and its subsequent amendments (Appendix 6).

Subject consent

Subjects were informed of the nature, purpose and known risk of the study both orally and in writing and gave their written informed consent before participating in the study (Appendices 1 and 2). Subjects were advised that they were free to withdraw from the study at any time without being obliged to give a reason. They were compensated for their time and inconvenience.

Indemnity provision

The Sponsor was responsible, without regard to legal liability, and indemnified Princeton Consumer Research, or any of their respective officers or employees in the event of claims for compensation from subjects suffering injury or other deterioration in health or well-being as a result of participation in this study, except and insofar as such claims arose as a result of any negligent act or omission on the part of

Princeton Consumer Research employees or any persons undertaking or involved in the study by arrangement with Princeton Consumer Research.

QUALITY ASSURANCE

The study was carried out in the spirit of the ICH Guidelines on Good Clinical Practice (1996) and other recognised guidelines. The draft report has been peer-reviewed for accuracy and completeness of presentation. Additionally, the study may also have been subject to the following Quality Assurance procedures:

- Review of protocol and protocol amendments for completeness, clarity and adequacy.
- Inspection and/or audit of critical phases of study conduct for compliance with protocol and Princeton Consumer Research procedures.

The Princeton Consumer Research Quality Assurance Manager would have informed Princeton Consumer Research management of any findings that may have affected the integrity of the study.

RETENTION OF DATA

All raw data generated by Princeton Consumer Research during the course of the study, and including protocol and final report, will be retained in the Princeton Consumer Research Archive for a minimum period of fifteen years from study completion. In the event of original data being transferred to the Sponsor at their request, exact copies will be so retained. At no time will archived data be destroyed without prior written approval of the Sponsor. All study data will be available at any time, by appointment, for inspection by the Sponsor or their authorised representative.

RESULTS

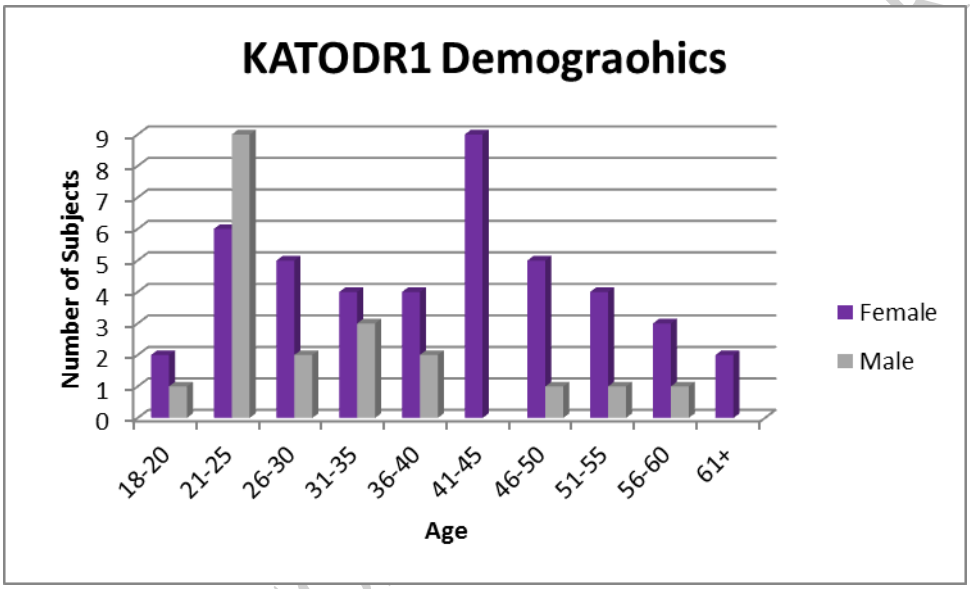
1 LOCATION AND DATES OF THE STUDY

The study was performed at Princeton Consumer Research, Princeton Forrestal Center, 307 College Road East, Princeton, NJ, 08540, USA, between 13th October 2014 and 24th October 2014.

2 SUBJECTS

64 subjects were recruited into the study and 49 subjects completed the study. The age composition of these subjects is presented in Figure 1. Eight subjects were removed from the study for non-compliance or withdrew due to reasons unrelated to the study.

FIGURE 1: AGE COMPOSITION OF THE SUBJECTS COMPLETING THE STUDY



3 ADVERSE EVENTS, ADVERSE REACTIONS AND SUBJECTS NOT COMPLETING THE STUDY

No adverse events or reactions were reported.

All subjects completed the study.

4 ASSESSMENTS

There was no statistically significant difference for the pre-treatment assessments between the test groups for any of the judges or between judges ($p>0.05$) so the study can be considered valid. Both the Test Article and Positive Control showed a highly statistically significant difference to the untreated baseline sites ($p<0.005$) in all assessments. All judges were statistically similar at all-time points and sites ($p>0.05$) and so assessments can be considered as accurate.

5 STATISTICAL OVERVIEW-

Baseline treatment assessments:

	J1	J2	J3	J4	Average
Mean Group 1	6.06	6.11	6.06	6.11	6.08
Mean Group 2	5.83	5.72	5.72	5.72	5.75
Mean Group 3	5.75	5.69	5.44	5.50	5.59

1 hour treatment assessments:

	J1	J2	J3	J4	Average
Mean Group 1	3.67	3.56	3.22	4.06	3.63
Mean Group 2	3.50	3.33	3.22	3.28	3.33
Mean Group 3	5.50	5.50	5.25	5.13	5.34

13 hours treatment assessments:

	J1	J2	J3	J4	Average
Mean Group 1	4.06	4.00	4.00	4.06	4.03
Mean Group 2	4.17	3.94	4.06	4.06	4.06
Mean Group 3	6.13	6.13	5.88	5.88	6.00

Within-treatment P-Value Assessments

	1	2	3
bl vs 1	2.57E-09	5.94E-11	3.73E-02
bl vs 13	1.30E-06	3.89E-04	7.09E-02

CONCLUSIONS

It can be concluded that for the test articles the claims of “breath freshening” and “freshens breath for over 12 hours” are valid.

APPENDIX 1: SUBJECT CONSENT FORM

Subject Number

PRINCETON CONSUMER RESEARCH

SUBJECT CONSENT for KATODR1 (AN ODOUR ASSESSMENT STUDY)

Name of Subject:……..

The nature of the trial and procedures required of the volunteers, together with possible hazards, have been described to me by the members of Princeton Consumer Research staff named below and I have had an opportunity to discuss these matters. Additionally I have been given a copy of the Subject Information Sheet for this trial.

I understand that the study will be conducted in compliance with the Standard Operating Procedures of Princeton Consumer Research which are available to me at my request and that I may withdraw from the study at any time without having to give a reason.

I understand that every effort has been made and will continue to be made by the Sponsors of this study and by Princeton Consumer Research medical personnel to ensure that the health status of the volunteers will not be adversely affected by their participation in this study. I understand that in the unlikely event of significant deterioration in health being caused by my participation in the study I will be given reasonable and appropriate medical treatment and may be compensated financially.

I also understand that all information given by me and all observations made on my health will be maintained in strictest confidence and in accordance with normal medical practice. This means the Sponsor of this study or an authorised representative of the Sponsor and/or representatives of regulatory authorities may request access to this information for checking purposes relevant to the study. Any such information will not identify me by name and this checking will be performed under the supervision of Princeton Consumer Research.

I agree to comply with the prohibitions and restrictions on the Subject Information Sheet and confirm that the information given on my questionnaires is true. I hereby consent to take part in the study and to carry out the procedures required of me. I also consent to my General Practitioner being informed of my participation and of any findings considered to require medical attention.

I consent to Princeton Consumer Research processing sensitive personal information that may be held by them or given by myself at the time of enrolment onto the above named study. This information will be treated as confidential to Princeton Consumer Research and will not be divulged to any third party unless required by Regulatory agencies. In all cases any information given will not identify me by name. This consent satisfies the requirement of the Data Protection Act 1998.

Signed: ..... Date: .....

I have explained the nature of the study to the above-named volunteer who has received a copy of the Subject Information Sheet.

Signed: ..... Date: .....

APPENDIX 2: SUBJECT INFORMATION SHEET – KATODR1

Please read this sheet carefully. It is a written explanation of the way in which the study will be performed. You will also be given an oral explanation of the study from members of Princeton Consumer Research staff and an opportunity to ask questions. If any further questions occur to you, please either ring the office or ask at the test centre. The aim of the study is to assess the level of odour in your breath.

Possible unwanted effects

In the very unlikely event that you are 'hypersensitive' to the products you might experience some shortness of breath, flushing and possibly dizziness. If this does happen you should remove the product and contact Princeton Consumer Research for advice. Should the shortness of breath become severe and you feel unwell contact your own doctor without delay. We would advise you of any products you should avoid.

Prohibitions and restrictions

Do not take aspirin or other non-steroidal anti-inflammatory drugs during the trial as these can have an effect on your irritant reaction.
If you require a painkiller for headaches etc., please take **only paracetamol.**
Do not use a sunbed or sunlamp during the trial and keep your arms out of natural sunlight during the trial as you could confuse irritation grading.
Do not have an immunisation, such as for travel, during the trial.
Let us know of any medication or change in your health during the trial as soon as possible as this could have an effect on your skin reaction.

TEST ARTICLES:	Toothpaste products. Product allocation will be randomised so that you will receive one of 3 different products. One group will not receive toothpaste and will remain untreated for 13 hours.
REGISTRATION STATUS:	Not applicable - Consumer Products.
TITLE/PURPOSE OF TRIAL:	To assess any effect by the products on breathe odour.
ATTENDANCE:	Please follow your study calendar and schedule
NUMBER OF PERSONS PARTICIPATING:	Approximately 63.
POSSIBLE RISKS/ DISCOMFORTS:	Irritation or allergic reaction to the test products, or their ingredients. In the very unlikely event that you are, 'hypersensitive', to the test products you might experience some shortness of breath, flushing and possibly dizziness.
PAYMENT DETAILS:	$ for completion of the study (If you are dropped due to a reaction, that, in the opinion of Princeton Consumer Research Inc is related to the product, then $ paid).

THE PROJECT SUPERVISOR IN CHARGE OF THIS STUDY MAY BE CONTACTED DURING AND OUTSIDE OF NORMAL WORKING HOURS ON **01621 859 230** (TRANSFER DURING OUT OF OFFICE HOURS FOR THE DURATION OF THE STUDY PERIOD ONLY).

APPENDIX 3: PRE-TREATMENT QUESTIONNAIRE

FOR OFFICE USE ONLY			
Subject's Initials			
MALE / FEMALE			

STRICTLY CONFIDENTIAL

In order for us to judge that you are healthy to take part in the patch test and that any medication you take is not likely to interfere with your test responses, we need information on your health. We may need to contact you again for further details but please answer all the questions as fully as possible.

STUDY No: KATODR1

Do you have any skin problems at present under your arms e.g. acne, pigment changes, psoriasis, eczema, skin cancer? ..... **YES** ☐ **NO** ☐

If 'YES' please give details of condition and/or treatment, eg ointment/cream.

_____

Are you regularly taking any medicines, drugs (including street drugs) or oral contraceptives at present? **YES** ☐ **NO** ☐

If 'YES' please give details eg name, how often taken.

_____

Have you ever had any operations? ..... **YES** ☐ **NO** ☐

If 'YES', please state when and for what.

_____

Have you ever had hepatic, renal, cardiac, pulmonary, digestive, haematological, neurological, locomotor, immune deficiency or psychiatric disease? ..... **YES** ☐ **NO** ☐

If 'YES', please give details.

_____

Have you consulted your doctor within the last 6 months? ..... **YES** ☐ **NO** ☐

If 'YES', please state when and for what.

_____

Have you ever been examined for suspected cancer? ..... **YES** ☐ **NO** ☐

If 'YES', please state when and for what. Was this confirmed as malignant?

_____

Have you ever had a reaction to drugs or medicine? ..... **YES** ☐ **NO** ☐

If 'YES', which drug and explain reaction and duration.

_____

Do you suffer from insulin-dependent or non insulin-dependent diabetes? ..... **YES** ☐ **NO** ☐

Do you suffer from epilepsy? ..... **YES** ☐ **NO** ☐

_____

PLEASE TURN OVER

How many units of alcohol do you consume **on average** in a week? _____
(A unit is ½ pint of beer or 1 glass of wine or 1 'short')

What is your maximum daily consumption? ____/units **OR** do you only drink on special occasions? ☐

Pregnancy.

Are you pregnant or breast feeding at present? ..... **YES** ☐ **NO** ☐

Is it possible that you will become pregnant? ..... **YES** ☐ **NO** ☐

If NO – Contraceptive Pill ☐ Name: ……..…… Condoms ☐ Sterilised ☐

Abstinence ☐ Vasectomy (partner) ☐ Post Menopausal ☐ Other (please specify) ☐

_____

Have you ever had any skin problems related to the use of any of the following types of material?

Material	**YES**	**NO**	**When? - Which products? – What happens?**
Toothpaste			
Mouthwash			
Floss			
Other-please specify			

a) Date of birth: _____ b) Age: _____

FOR OFFICE USE ONLY

Questionnaire checked by: _____ Date: _____ Medication checked by:_____ Date: _____

TO BE COMPLETED WHEN BOOKING VOLUNTEER ONTO STUDY

Has the volunteer had a fever in the last 12 hours? _____ **YES☐NO☐**

Has the volunteer used self tanning lotion on the arms in the last week ? **YES☐NO☐**

Has the volunteer taken any new medication in the last 7 days ? **YES☐NO☐**

Comments:_____

Subject can/cannot proceed with test. Reason for exclusion:_____

Subject accepted onto study by: _____ Date: _____

Subject No: ☐

APPENDIX 4: TEST ARTICLE INGREDIENT LISTINGS

1. Article 197-75B

INCI Ingredient Name	CAS Number	% W/W	Function
Active Ingredient			
SODIUM FLUORIDE	7681-49-4	0.24	Anticaries Agent
Other Ingredients			
WATER(AQUA)	7732-18-5	31.066305	Solvent
SORBITOL	50-70-4	22.75	Flavoring Agent
GLYCERIN	56-81-5	22.529845	Oral Care Agent
HYDRATED SILICA	112926-00-8	15.386	Abrasive
FLAVOR	N/A	2.125	Flavoring Agent
XYLITOL	87-99-0	1.75	Flavoring Agent
TETRAPOTASSIUM PYROPHOSPHATE	7320-34-5	1.00	Oral Care Agent
TETRASODIUM PYROPHOSPHATE	7722-88-5	1.00	Oral Care Agent
CELLULOSE GUM	9004-32-4	0.65	Thickening Agent
SODIUM BENZOATE	532-32-1	0.50005	Preservative
ALOE BARBADENSIS (ALOE VERA) LEAF JUICE	85507-69-3	0.4965	Flavoring Agent
SODIUM CHLORITE	7758-19-2	0.10	Oral Care Agent
AMMONIUM GLYCYRRHIZATE	53956-04-0	0.09	Flavoring Agent
ASCORBIC ACID	50-81-7	0.0011	Antioxidant
FRAGRANCE (PARFUM)	N/A	0.00089	Fragrance
MENTHA VIRIDIS (SPEARMINT) LEAF OIL	8008-79-5	0.00008	Flavoring Agent
MENTHA ARVENSIS (CORNMINT) LEAF OIL	68917-18-0	0.00003	Flavoring Agent

APPENDIX 5 - ODOUR

ODOUR ASSESSMENT PROCEDURE

Princeton # KATODR1

Malodour judge evaluations will be performed by four expert odour judges in well-ventilated air-conditioned rooms maintained at a reasonable cool temperature and humidity. Judge evaluation rooms will have 3M air filtration units or similar operating during evaluation visits to reduce the level of fragrance and malodour in the air.

Malodour evaluations will be conducted by all judges who wish to test for qualification for this study. There will be two (2) evaluation time points during the study to determine the efficacy of treatment(s): 1) baseline for qualification [The subject's baseline malodour grades will be averaged from the four most experienced judges and the average grade for each subject must be a 4.0 or greater in order for the subject to qualify for the Treatment phase of the study] and 2) approximately 1 and 12 hrs, following the treatment.

At each judge station please provide cones for sniffing and a box of tissues to help cleanse sinuses.

20-Subject Cohort: Twenty subjects will be assigned to the same product treatment for the entire treatment phase of the study.

Consensus Subjects/Grading: One subject will be randomly selected at Baseline, Study Day 1, for consensus judging. These subjects will follow all the same study procedures as the other subjects.

The odour judges will always evaluate the consensus subject prior to evaluating each of the twenty subjects in the treatment cohort. The judges will discuss their odour grades for the consensus subject until they are aligned on the odour scale prior to evaluating the subject cohort being treated with the same product.

The judge number will be recorded for each subject's first evaluation at each evaluation interval. The subjects will see each judge in random order. After approaching the judge, the subjects will keep their mouths open and not blow out. The odour judge will use pre-cut cups (~ 4" diameter at wide end, ~2" diameter at narrow end and ~ 2" long) and place the wide end of a fresh unused cup tightly against the bottom lip of the subject. The judge will sniff by placing the nose against the narrow end of the cup. When completed, the cup will be discarded. There will be an approximate 60-second waiting period between subjects.

Malodour Scale*

0 = None, no malodour
1 = Threshold malodour
2 = Very slight malodour
3 = Slight malodour
4 = Slight to moderate malodour
5 = Moderate malodour
6 = Slightly strong malodour
7 = Moderately strong malodour
8 = Strong malodour
9 = Very strong malodour
10 = Extremely strong malodour

OFF ODOURS NOTATION 1
T = Smoke
P = Perfume (Fragrance)
A= Alcohol
S= Soap
O=Other

The off odour notations will be used primarily during the Baseline qualification odour evaluation to assist in subject selection. If a subject has a strong off-odour indicating non-compliance they may be excused from participation. Off odour notations will be used on Day 6 odour evaluations only when the judges are unable to score malodour due to an off odour

APPENDIX 7: DECLARATION OF HELSINKI

WORLD MEDICAL ASSOCIATION DECLARATION OF HELSINKI
Ethical Principles for Medical Research Involving Human Subjects

Adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964, and amended by the:
29th WMA General Assembly, Tokyo, Japan, October 1975
35th WMA General Assembly, Venice, Italy, October 1983
41st WMA General Assembly, Hong Kong, September 1989
48th WMA General Assembly, Somerset West, Republic of South Africa, October 1996
52nd WMA General Assembly, Edinburgh, Scotland, October 2000
53th WMA General Assembly, Washington 2002 (Note of Clarification on paragraph 29 added)
55th WMA General Assembly, Tokyo 2004 (Note of Clarification on Paragraph 30 added)
59th WMA General Assembly, Seoul, October 2008

A. INTRODUCTION

1. The World Medical Association (WMA) has developed the Declaration of Helsinki as a statement of ethical principles for medical research involving human subjects, including research on identifiable human material and data.

The Declaration is intended to be read as a whole and each of its constituent paragraphs should not be applied without consideration of all other relevant paragraphs.

2. Although the Declaration is addressed primarily to physicians, the WMA encourages other participants in medical research involving human subjects to adopt these principles.
3. It is the duty of the physician to promote and safeguard the health of patients, including those who are involved in medical research. The physician's knowledge and conscience are dedicated to the fulfilment of this duty.
4. The Declaration of Geneva of the WMA binds the physician with the words, "The health of my patient will be my first consideration," and the International Code of Medical Ethics declares that, "A physician shall act in the patient's best interest when providing medical care."
5. Medical progress is based on research that ultimately must include studies involving human subjects. Populations that are underrepresented in medical research should be provided appropriate access to participation in research.
6. In medical research involving human subjects, the well-being of the individual research subject must take precedence over all other interests.
7. The primary purpose of medical research involving human subjects is to understand the causes, development and effects of diseases and improve preventive, diagnostic and therapeutic interventions (methods, procedures and treatments). Even the best current interventions must be evaluated continually through research for their safety, effectiveness, efficiency, accessibility and quality.
8. In medical practice and in medical research, most interventions involve risks and burdens.
9. Medical research is subject to ethical standards that promote respect for all human subjects and protect their health and rights. Some research populations are particularly vulnerable and need special protection. These include those who cannot give or refuse consent for themselves and those who may be vulnerable to coercion or undue influence.
10. Physicians should consider the ethical, legal and regulatory norms and standards for research involving human subjects in their own countries as well as applicable international norms and standards. No national or international ethical, legal or regulatory requirement should reduce or eliminate any of the protections for research subjects set forth in this Declaration.

APPENDIX 7 - Continued

B. BASIC PRINCIPLES FOR ALL MEDICAL RESEARCH

11. It is the duty of physicians who participate in medical research to protect the life, health, dignity, integrity, right to self-determination, privacy, and confidentiality of personal information of research subjects.
12. Medical research involving human subjects must conform to generally accepted scientific principles, be based on a thorough knowledge of the scientific literature, other relevant sources of information, and adequate laboratory and, as appropriate, animal experimentation. The welfare of animals used for research must be respected.
13. Appropriate caution must be exercised in the conduct of medical research that may harm the environment.
14. The design and performance of each research study involving human subjects must be clearly described in a research protocol. The protocol should contain a statement of the ethical considerations involved and should indicate how the principles in this Declaration have been addressed. The protocol should include information regarding funding, Sponsors, institutional affiliations, other potential conflicts of interest, incentives for subjects and provisions for treating and/or compensating subjects who are harmed as a consequence of participation in the research study. The protocol should describe arrangements for post-study access by study subjects to interventions identified as beneficial in the study or access to other appropriate care or benefits.
15. The research protocol must be submitted for consideration, comment, guidance and approval to a research ethics committee before the study begins. This committee must be independent of the researcher, the Sponsor and any other undue influence. It must take into consideration the laws and regulations of the country or countries in which the research is to be performed as well as applicable international norms and standards but these must not be allowed to reduce or eliminate any of the protections for research subjects set forth in this Declaration. The committee must have the right to monitor ongoing studies. The researcher must provide monitoring information to the committee, especially information about any serious adverse events. No change to the protocol may be made without consideration and approval by the committee.
16. Medical research involving human subjects must be conducted only by individuals with the appropriate scientific training and qualifications. Research on patients or healthy volunteers requires the supervision of a competent and appropriately qualified physician or other health care professional. The responsibility for the protection of research subjects must always rest with the physician or other health care professional and never the research subjects, even though they have given consent.
17. Medical research involving a disadvantaged or vulnerable population or community is only justified if the research is responsive to the health needs and priorities of this population or community and if there is a reasonable likelihood that this population or community stands to benefit from the results of the research.
18. Every medical research study involving human subjects must be preceded by careful assessment of predictable risks and burdens to the individuals and communities involved in the research in comparison with foreseeable benefits to them and to other individuals or communities affected by the condition under investigation.
19. Every clinical trial must be registered in a publicly accessible database before recruitment of the first subject.
20. Physicians may not participate in a research study involving human subjects unless they are confident that the risks involved have been adequately assessed and can be satisfactorily managed. Physicians must immediately stop a study when the risks are found to outweigh the potential benefits or when there is conclusive proof of positive and beneficial results.

APPENDIX 7 - Continued

21. Medical research involving human subjects may only be conducted if the importance of the objective outweighs the inherent risks and burdens to the research subjects.
22. Participation by competent individuals as subjects in medical research must be voluntary. Although it may be appropriate to consult family members or community leaders, no competent individual may be enrolled in a research study unless he or she freely agrees.
23. Every precaution must be taken to protect the privacy of research subjects and the confidentiality of their personal information and to minimize the impact of the study on their physical, mental and social integrity.
24. In medical research involving competent human subjects, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail, and any other relevant aspects of the study. The potential subject must be informed of the right to refuse to participate in the study or to withdraw consent to participate at any time without reprisal. Special attention should be given to the specific information needs of individual potential subjects as well as to the methods used to deliver the information. After ensuring that the potential subject has understood the information, the physician or another appropriately qualified individual must then seek the potential subject's freely-given informed consent, preferably in writing. If the consent cannot be expressed in writing, the non-written consent must be formally documented and witnessed.
25. For medical research using identifiable human material or data, physicians must normally seek consent for the collection, analysis, storage and/or reuse. There may be situations where consent would be impossible or impractical to obtain for such research or would pose a threat to the validity of the research. In such situations the research may be done only after consideration and approval of a research ethics committee.
26. When seeking informed consent for participation in a research study the physician should be particularly cautious if the potential subject is in a dependent relationship with the physician or may consent under duress. In such situations the informed consent should be sought by an appropriately qualified individual who is completely independent of this relationship.
27. For a potential research subject who is incompetent, the physician must seek informed consent from the legally authorized representative. These individuals must not be included in a research study that has no likelihood of benefit for them unless it is intended to promote the health of the population represented by the potential subject, the research cannot instead be performed with competent persons, and the research entails only minimal risk and minimal burden.
28. When a potential research subject who is deemed incompetent is able to give assent to decisions about participation in research, the physician must seek that assent in addition to the consent of the legally authorized representative. The potential subject's dissent should be respected.
29. Research involving subjects who are physically or mentally incapable of giving consent, for example, unconscious patients, may be done only if the physical or mental condition that prevents giving informed consent is a necessary characteristic of the research population. In such circumstances the physician should seek informed consent from the legally authorized representative. If no such representative is available and if the research cannot be delayed, the study may proceed without informed consent provided that the specific reasons for involving subjects with a condition that renders them unable to give informed consent have been stated in the research protocol and the study has been approved by a research ethics committee. Consent to remain in the research should be obtained as soon as possible from the subject or a legally authorized representative.

APPENDIX 7 - Continued

30. Authors, editors and publishers all have ethical obligations with regard to the publication of the results of research. Authors have a duty to make publicly available the results of their research on human subjects and are accountable for the completeness and accuracy of their reports. They should adhere to accepted guidelines for ethical reporting. Negative and inconclusive as well as positive results should be published or otherwise made publicly available. Sources of funding, institutional affiliations and conflicts of interest should be declared in the publication. Reports of research not in accordance with the principles of this Declaration should not be accepted for publication.

C. ADDITIONAL PRINCIPLES FOR MEDICAL RESEARCH COMBINED WITH MEDICAL CARE

31. The physician may combine medical research with medical care only to the extent that the research is justified by its potential preventive, diagnostic or therapeutic value and if the physician has good reason to believe that participation in the research study will not adversely affect the health of the patients who serve as research subjects.
32. The benefits, risks, burdens and effectiveness of a new intervention must be tested against those of the best current proven intervention, except in the following circumstances:

- The use of placebo, or no treatment, is acceptable in studies where no current proven intervention exists; or
- Where for compelling and scientifically sound methodological reasons the use of placebo is necessary to determine the efficacy or safety of an intervention and the patients who receive placebo or no treatment will not be subject to any risk of serious or irreversible harm. Extreme care must be taken to avoid abuse of this option.

33. At the conclusion of the study, patients entered into the study are entitled to be informed about the outcome of the study and to share any benefits that result from it, for example, access to interventions identified as beneficial in the study or to other appropriate care or benefits.
34. The physician must fully inform the patient which aspects of the care are related to the research. The refusal of a patient to participate in a study or the patient's decision to withdraw from the study must never interfere with the patient-physician relationship.
35. In the treatment of a patient, where proven interventions do not exist or have been ineffective, the physician, after seeking expert advice, with informed consent from the patient or a legally authorized representative, may use an unproven intervention if in the physician's judgement it offers hope of saving life, re-establishing health or alleviating suffering. Where possible, this intervention should be made the object of research, designed to evaluate its safety and efficacy. In all cases, new information should be recorded and, where appropriate, made publicly available.

APPENDIX 8: RAW DATA - INDIVIDUAL MEASUREMENTS

KATODR1 - Assessor 1				
Subject No	Baseline	1 hour	13 hours	comments
1	8	7	7	
2				
3	6	4	4	
4	6	4	3	*Food smell
5	5	2	3	
6				
7	6	3	5	
8	6	4	4	
9	6	3	5	*Garlic
10	7	5	5	
11	6	4	5	
12	4	2	2	
13	4	2	4	
14	6	3	2	
15	6	3	2	
16	8	3	3	
17	7	5	5	
18	7	3	5	
19	6	4	5	
20	5	5	4	
21				
22				
23	5	3	3	
24	5	3	3	
25	5	2	3	
26				
27	6	4	5	*Coffee
28	6	5	4	
29	6	3	4	
30	5	2	2	
31	6	3	4	
32				
33	5	3	4	
34	5	4	3	
35	7	4	5	*Food smell
36	7	4	5	*Coffee
37	6	3	5	
38	7	3	5	
39	8	5	6	*Garlic
40	5	4	5	
41	5	4	4	
42	6	4	5	
43				
44	5	4	5	
45	4	3	4	
46	6	5	5	
47	8	8	8	
48	5	5	6	
49	6	6	6	
50				
51	4	4	4	
52				
53	6	6	6	
54	5	5	5	
55				
56				
57	8	6	8	
58	8	8	8	
59	6	6	8	
60	5	5	6	
61	6	8	8	
62				
63	5	5	6	
64	5	4	5	

KATODR1 - Assessor 2				
Subject No	Baseline	1 hour	13 hours	comments
1	8	5	5	
2				
3	6	4	4	
4	6	4	4	*Food spice
5	5	2	3	
6				
7	6	3	5	
8	6	3	4	
9	6	5	5	*Food spice
10	7	5	5	
11	6	4	5	
12	4	2	2	
13	4	3	3	
14	6	2	2	
15	6	3	3	
16	8	2	3	
17	7	5	5	
18	8	4	5	
19	6	5	5	
20	5	3	4	
21				
22				
23	5	3	3	
24	5	3	3	
25	5	3	3	
26				
27	6	4	5	*Coffee
28	6	5	4	
29	6	3	3	
30	5	3	3	
31	6	2	2	
32				
33	5	3	4	
34	5	3	3	
35	6	4	5	
36	6	4	5	*Coffee
37	6	3	5	
38	7	3	5	
39	8	5	6	*Garlic
40	5	2	3	
41	5	3	4	
42	6	4	5	
43				
44	5	5	5	
45	4	4	4	
46	6	5	5	
47	8	8	8	
48	8	8	8	
49	6	6	6	
50				
51	4	3	4	
52				
53	6	6	6	
54	5	4	5	
55				
56				
57	8	8	8	
58	4	5	6	
59	6	6	8	
60	5	5	6	
61	6	6	8	
62				
63	5	5	6	
64	5	4	5	

KATODR1 - Assessor 3				
Subject No	Baseline	1 hour	13 hours	comments
1	8	5	5	
2				
3	6	4	4	
4	6	4	4	*Food Spice
5	5	2	3	
6				
7	6	3	5	
8	6	3	4	
9	6	3	5	*Garlic
10	7	5	5	
11	6	4	5	
12	4	2	2	
13	4	2	4	
14	6	3	2	
15	6	1	2	
16	8	2	3	
17	7	4	5	
18	7	3	5	
19	6	5	5	
20	5	3	4	
21				
22				
23	5	3	3	
24	5	3	3	
25	5	2	3	
26				
27	6	4	5	*coffee
28	6	4	4	
29	6	3	4	
30	5	3	4	
31	6	2	2	
32				
33	5	3	4	
34	5	3	3	
35	6	4	5	*Food
36	6	4	5	*coffee
37	6	3	5	
38	7	3	5	
39	8	5	6	*Garlic
40	5	2	3	
41	5	3	4	
42	6	4	5	
43				
44	5	5	5	
45	4	3	4	
46	5	5	5	
47	8	8	8	
48	5	4	4	
49	6	6	6	
50				
51	4	4	4	
52				
53	6	6	6	
54	5	4	5	
55				
56				
57	8	8	8	
58	4	5	6	
59	6	6	8	
60	5	5	6	
61	6	6	8	
62				
63	5	5	6	
64	5	4	5	

KATODR1 - Assessor 4				
Subject No	Baseline	1 hour	13 hours	comments
1	8	7	5	
2				
3	6	4	4	
4	6	4	3	*Food Spice
5	5	2	3	
6				
7	7	4	5	
8	6	3	4	
9	6	5	5	*Garlic
10	7	5	5	
11	6	4	5	
12	4	2	2	
13	4	3	4	
14	6	4	2	
15	6	4	2	
16	8	5	3	
17	7	5	7	
18	7	4	5	
19	6	5	5	
20	5	3	4	
21				
22				
23	5	3	3	
24	5	3	3	
25	5	2	3	
26				
27	6	4	5	*Coffee
28	6	5	4	
29	6	3	4	
30	5	3	4	
31	6	2	2	
32				
33	5	3	4	
34	5	3	3	
35	6	4	5	
36	6	4	5	*Coffee
37	6	3	5	
38	7	3	5	
39	8	5	6	*Garlic
40	5	2	3	
41	5	3	4	
42	6	4	5	
43				
44	5	5	5	
45	4	3	4	
46	6	6	5	
47	8	8	8	
48	5	3	3	
49	6	6	6	
50				
51	4	4	4	
52				
53	6	6	6	
54	5	5	6	
55				
56				
57	8	8	8	
58	4	5	6	
59	6	6	8	
60	5	3	6	
61	6	5	8	
62				
63	5	5	6	
64	5	4	5	

APPENDIX 8: RAW DATA - MEAN MEASUREMENTS

	Mean scores - Article 1		
	Baseline	1 hour	13 hours
1	8	6	6
2			
3	6	4	4
4	6	4	4
5	5	2	3
6			
7	6	3	5
8	6	3	4
9	6	4	5
10	7	5	5
11	6	4	5
12	4	2	2
13	4	3	4
14	6	3	2
15	6	3	2
16	8	3	3
17	7	5	6
18	7	4	5
19	6	5	5
20	5	4	4
21			
Mean	6	4	4

	Mean scores - Article 2		
	Baseline	1 hour	13 hours
22			
23	5	3	3
24	5	3	3
25	5	2	3
26			
27	6	4	5
28	6	5	4
29	6	3	4
30	5	3	3
31	6	2	3
32			
33	5	3	4
34	5	3	3
35	6	4	5
36	6	4	5
37	6	3	5
38	7	3	5
39	8	5	6
40	5	3	4
41	5	3	4
42	6	4	5
43			
Mean	6	3	4

	Mean scores - Article 3		
	Baseline	1 hour	13 hours
44	5	5	5
45	4	3	4
46	6	5	5
47	8	8	8
48	6	5	5
49	6	6	6
50			
51	4	4	4
52			
53	6	6	6
54	5	5	5
55			
56			
57	8	8	8
58	5	6	7
59	6	6	8
60	5	5	6
61	6	6	8
62			
63	5	5	6
64	5	4	5
Mean	6	5	6