

Attachment B.

**National Health and Nutrition Examination Survey (NHANES)
THAI Fluorosis Methodology Study**

**OMB no. 0920-0237
Expires: 12/31/2011**

Assurance of confidentiality – All information which would permit identification of an individual, a practice, or an establishment will be held confidential, will be used for statistical purposes only by NCHS staff, contractors, and agents only when required and with necessary controls, and will not be disclosed or released to other persons without the consent of the individual or establishment in accordance with section 308(d) of the Public Health Service Act (42 USC 242m) and the Confidential Information Protection and Statistical Efficiency Act (PL-107-347).

Public reporting burden of this collection of information is estimated to average 15 minute per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Reports Clearance Officer; 1600 Clifton Road, MS D-74, Atlanta, GA 30333. ATTN: PRA (0920-0237).

APPENDIX C

SCREENING FORM AND

EXAMPLE OF REJECTION NOTIFICATION INFORMATION

SCREENING FORM

Adhesive label to contain the following information;

Initials, Class, School & ID

- | | | |
|--|-----|----|
| 1. Is subject in good health?
(list medications, allergies, in comments section) | Yes | No |
| 2. Does the subject have a complete record from the previous study? | Yes | No |
| 3. Does subject have sufficient teeth (all four permanent molars) available for examination? | Yes | No |
| 4. Is the subject free from bonded orthodontic appliances? | Yes | No |
| 5. Has parent/guardian signed an Informed Consent Form? | Yes | No |

If any answer to the questions above is No the subject is ineligible for study and the subject should be given a rejection notification slip and Question 6 completed (No). If all answers are Yes the subject is eligible to take part in the study and Question 6 should be completed Yes.

- | | | |
|--|-----|----|
| 6. IS SUBJECT ELIGIBLE FOR ENTRY INTO STUDY? | Yes | No |
| If no has "rejection notification" been sent to parent | Yes | No |
| 7. Has the child agreed to take part in the study and have they provided consent to do so? | Yes | No |

COMMENTS

Signature of screener

Date _____

Adhesive label to contain the following information;

Initials, Class, School & ID

Oral Health Study II

Dear parent,

Your child had a dental examination today as part of the Oral Health Study. Unfortunately we were unable to include them in the study for the reason indicated below.

Thank you for agreeing to help us with this study.

If you require any further information please contact

Assoc. Prof. Patcharawan Srisilapanan

APPENDIX D

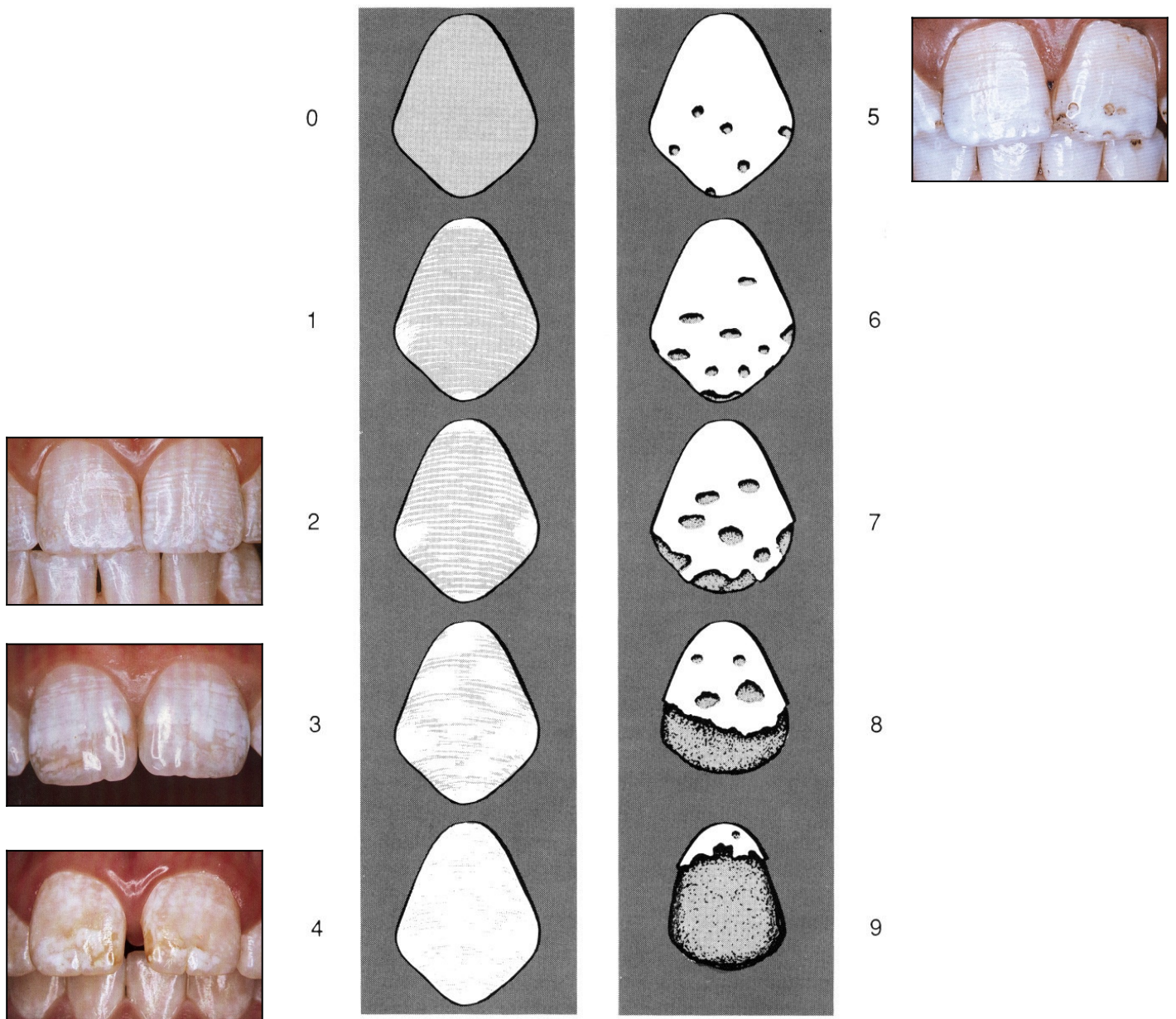
TF SCORING INDEX

DDE INDEX

DEANS INDEX

THE TF INDEX FOR FLUOROSIS

This is the diagrammatic representation of the TF index. Compare these to the clinical images which are included for comparison.



DDE INDEX

	CODE
Normal	0
<i>Demarcated opacities</i>	
White/cream	1
Yellow/brown	2
<i>Diffuse opacities:</i>	
Diffuse – lines	3
Diffuse – patchy	4
Diffuse – confluent	5
Confluent/patchy + staining + loss of enamel	6
<i>Hypoplasia:</i>	
Pits	7
Missing enamel	8
Any other defects	9
<i>Combinations:</i>	
Demarcated and diffuse	A
Demarcated and hypoplasia	B
Diffuse and hypoplasia	C
All three defects	D
<i>Extent of Defect:</i>	
Normal	0
Less than 1/3	1
At least 1/3 – 2/3	2
At least 2/3	3

DEANS INDEX

Score	Criteria
Normal	The enamel represents the usual translucent semivitriform type of structure. The surface is smooth, glossy, and usually of a pale creamy white color.
Questionable	The enamel discloses slight aberrations from the translucency of normal enamel, ranging from a few white flecks to occasional white spots. This classification is utilized in those instances where a definite diagnosis of the mildest form of fluorosis is not warranted and a classification of "normal" is not justified.
Very Mild	Small opaque, paper white areas scattered irregularly over the tooth but not involving as much as 25% of the tooth surface. Frequently included in this classification are teeth showing no more than about 1-2 mm of white opacity at the tip of the summit of the cusps of the bicuspid or second molars.
Mild	The white opaque areas in the enamel of the teeth are more extensive but do not involve as much as 50% of the tooth.
Moderate	All enamel surfaces of the teeth are affected, and the surfaces subject to attrition show wear. Brown stain is frequently a disfiguring feature.
Severe	Includes teeth formerly classified as "moderately severe and severe." All enamel surfaces are affected and hypoplasia is so marked that the general form of the tooth may be affected. The major diagnostic sign of this classification is discrete or confluent pitting. Brown stains are widespread and teeth often present a corroded-like appearance

APPENDIX E

DATA COLLECTION CHARTS

Chiang Mai Fluoride Study II

Visual Examination Form TF

Clinical Examiner: _____ Scribe: _____
Date: _____

*Adhesive label to contain the following information;
Initials, Class, School & ID*

SUBJECT HAPPY TO CONTINUE ON STUDY: YES NO (Circle)

Tooth	1.4	1.3	1.2	1.1	2.1	2.2	2.3	2.4
TF Score								
DDE Score								

Top copy to be sent to Manchester; Bottom Copy to be retained in Chiang Mai

.....
If Examination is repeat please tick box
.....

Chiang Mai Fluoride Study II

Visual Examination Form DEANS

Clinical Examiner: _____ Scribe: _____
 Date: _____

Adhesive label to contain the following information;
 Initials, Class, School & ID

SUBJECT HAPPY TO CONTINUE ON STUDY: YES NO (Circle)

Tooth	1.4	1.3	1.2	1.1	2.1	2.2	2.3	2.4
DEANS SCORE								

If Examination is repeat please tick box

Top copy to be sent to Manchester; Bottom Copy to be retained in Chiang Mai

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Top copy to be sent to Manchester; Bottom Copy to be retained in Chiang Mai

If Examination is repeat please tick box

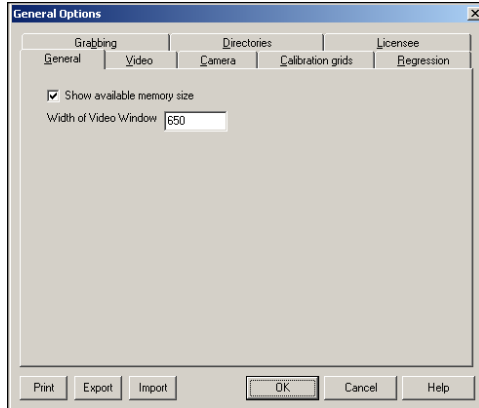
APPENDIX F

QLF AND PHOTOGRAPHIC PROTOCOLS

QLF Protocol for fluorosis imaging.

Software Settings:

The following settings should be applied to the QLF software (QLF Patient) and also to the Jai Camera Software. Any variation in image size or appearance should first be investigated by confirming that these settings are correct. A copy of these settings should be placed on the appropriate computer for ease of use. The unit should be switched on 30 minutes before the first subject is imaged to ensure that the light source is stable.



The window size should be 650 pixels. This is a width measurement and will permit the maximum image size to be acquired. Images of differing sizes will require different blur levels when analysed and therefore it is essential that this is maintained throughout the study.

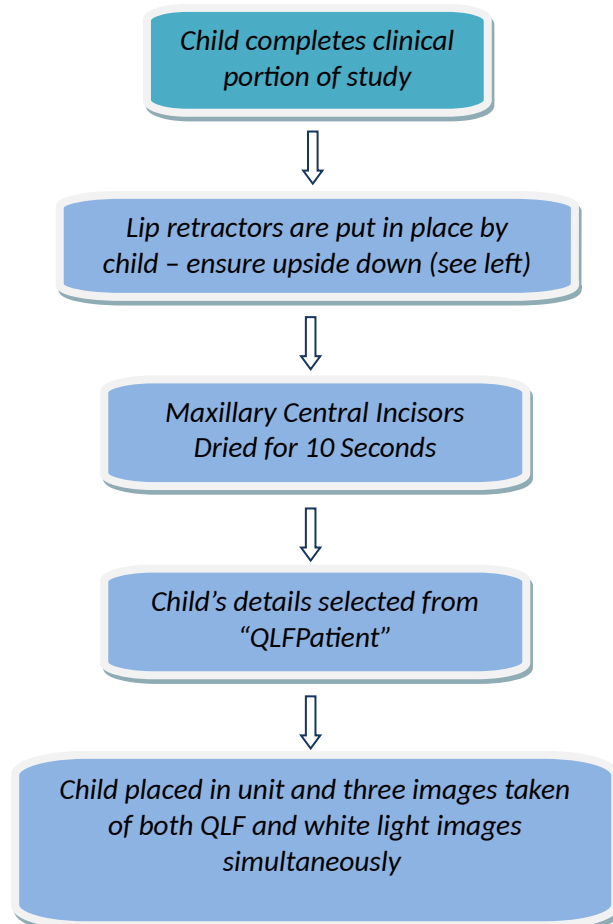
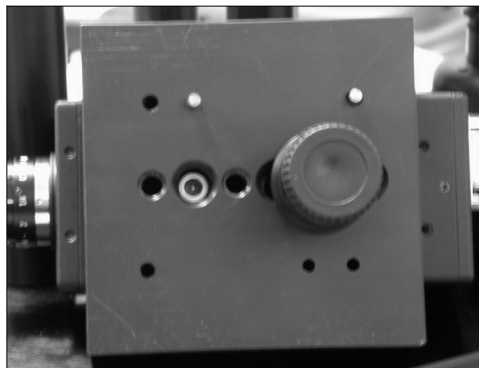
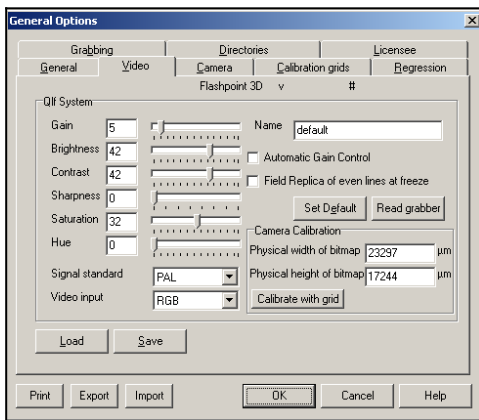
Image options. The gain, brightness, contrast and saturation should be maintained at the levels shown below. Variations in these will prevent analysis.

The final image demonstrates the mounting of the camera to the geometry device. The distance between the camera and the light source is crucial and therefore if the camera is dissembled the operator should check this before commencing imaging.

File storage and backup:

All images will be stored in a folder called "QLFData" this will be on the route of the hard drive (i.e. c:/QLFData). At the end of each session this folder should be backed up on to an external hard drive which should be stored separately from the computer. The photographic images will also be placed on the same drive, as will the images from the intra-oral camera.

Imaging protocol:



APPENDIX G

TREATMENT REQUIRED FORM EXAMPLE

TREATMENT REQUIRED FORM EXAMPLE

*Adhesive label to contain the
following information;*

Initials, Class, School & ID

To be completed by the examining dentist

We have checked your child's teeth as part of a clinical trial that you agreed to by signing a consent form.

When we examined your child's teeth we thought that they would benefit from some additional treatment; we would therefore

a. recommend a dental inspection in a dental surgery as a matter of urgency

b. recommend a dental inspection in a dental surgery within the next few months

Comment from dentist:

If your child does not have a dentist or you are having difficulty finding a dentist please contact our main dental clinic for advice:.