To compare patient experience using two ultrasonic scalers, a magnetostrictive stack scaler with a piezoelectric scaler, in the maintenance of periodontal stability.

WH/NW – 11/16

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Summary Information

Title:	To compare patient experience using two ultrasonic scalers, a magnetostrictive stack scaler with a piezoelectric scaler, in the maintenance of periodontal stability.
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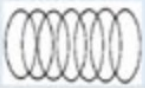
INTRODUCTION

Periodontal disease is a common condition affecting 50% of the population (Kassebaum et al 2015), causing bleeding of the gingivae, recession (gum shrinkage) and bone loss around the teeth which may result in tooth loss if the condition is untreated (Kassebaum 2015). Tooth loss can impact on quality of life as it may become more difficult to chew and missing teeth can make people self-conscious of their appearance and less confident. Following periodontal treatment patients need to be seen on a 3 monthly basis to attempt to maintain stability (Axelsson & Lindhe 1981). This supportive periodontal treatment (maintenance phase) comprises of cleaning of the gingival crevice and disruption of the biofllm and is usually performed with powered scalers although hand instruments can also be used. Studies have shown the beneficial impact of regular supportive periodontal therapy/maintenance. There is very strong evidence that structured maintenance and good oral hygiene is successful in maintaining periodontal attachment levels and preventing tooth loss (Ramfjord et al 1982).

There are two main types of powered scaler, sonic and ultrasonic. Sonic scaler tips move in an orbital pattern, tracing the letter "O" as they vibrate at approximately 3 to 9 kHz. Ultrasonic scalers vibrate at much higher frequencies (25kHz, per second or higher). The pattern of vibration is much more linear than the sonic scaler, tracing the letter "I" or a very narrow ellipse as it vibrates. The primary difference between sonic and ultrasonic scalers is that the ultrasonic scalers use irrigation which is far more effective at disrupting the biofilm, critical to the treatment and maintenance of stability of periodontal disease due to acoustic water streaming and cavitation of air bubbles in the water stream.

There are two types of ultrasonic device, magnetostrictive devices (eg Cavitron®) where the tip vibrations are created by a resonating stack of metal strips on the back of the insert with the tips vibrating at a frequency of 20 kHz to 40 kHz. The other type of device is the piezoelectric scaler devices (eg Tigon®) when the vibrations are produced by oscillations of a quartz crystal in the handpiece at a frequency of 29kHz to 50kHz). The strokes occur in a linear pattern via crystals activated by the ceramic headpiece. An illustration showing a comparison of the two types of scaler is shown below:

Comparison of Ultrasonic Scalers		
	Magnetostrictive	**Piezoelectric**
Frequency	20 – 40 kHz	29 – 50 kHz
Stroke Pattern	Elliptical 	Linear 
Energy Conversion	Metal rod or stack of metal sheets	Crystals activated by ceramic handpiece
Power Dispersion	All surfaces active	Only active on lateral sides

The energy dispersion for the magnetostrictive power scaler makes all its sides effective. The energy output at the tip produces the greatest amount of vibration which can cause damage and discomfort to the patient. The energy dispersion for the piezoelectric scaler differs as only the lateral sides of the tip are effective, the most effective portion of the tip is the last 2.4 mm, and it thought to cause less damage and patient discomfort (Yousefimanesh et al 2012).

An advantage of the piezoelectric device is that it requires less water to control heat, reducing damage to the tissues with overheating. Metal stacks on magnetostrictive inserts can be easily bent, which could impair vibration and overall function. This is not an issue for the piezo since the entire handpiece does not vibrate, and further there may be greater tactile sensitivity with the piezo. The piezoelectric handpiece is also wider and therefore more ergonomically designed than the thinner magnetostrictive one.

The metal stack in the magnetostrictive scaler generates heat and copious cold water irrigation is needed to prevent overheating. The quartz crystal in the piezo scaler generates relatively little heat, so the device can be used safely with very little water irrigation. Piezo devices can also have a separate water warmer application as water is not needed to cool the piezo. Magnetostrictive scalers must not use warm water, only cold water to cool the stack. The use of warm water in the piezo scaler could potentially improve patient comfort during treatment for those whose teeth are sensitive to cold water. The majority of patients who have periodontal disease also exhibit tooth sensitivity as a result of gum recession, Chabansky documenting this figure as high as 84%.

Study Design

The study is designed to compare the patient experience between the piezo Tigon+® ultrasonic scaler and the magnetstrictive Cavitron Select SPS 30K® ultrasonic scaler for treating periodontally susceptible individuals in periodontal maintenance phase of dental treatment. Comparisons will be made from the patient experience with regards to discomfort, noise and vibration between the two ultrasonics. Furthermore, we will assess whether the

additional feature of using warm water with the Tigon ultrasonic unit is of value to the patient experience.

The study will be conducted by the Bristol Dental Clinical Trials Unit set within a general dental practice recruiting private patients.

AIM

1. Primary aim

To determine patient experience (pain/discomfort, vibration, noise) during ultrasonic tooth scaling as part of a periodontal maintenance visit using a piezo-device compared to a magnetostrictive-device with room temperature water used in both devices for irrigation. The primary outcome measure is discomfort

2. Secondary aim

To determine patient experience (pain/discomfort, vibration, noise) during ultrasonic tooth scaling as part of a periodontal maintenance visit using a piezo-device irrigated by warm water compared to a magnetostrictive-device with room temperature water for irrigation. The primary outcome measure is discomfort

STUDY DESIGN

This is a single centre, blind (with respect to the patient), randomised, split mouth design, crossover study in periodontally susceptible patients in maintenance phase undergoing supportive periodontal therapy. The study is split-mouth, with regard to side, and simultaneously crossover with regard to treatment order.

Eligible participants will be randomly allocated to receive one of the two treatment procedures, A or B, according to a predetermined randomisation schedule (2 treatments per visit – split mouth). The treatment procedures are as follows:

A1. Ultrasonic scaling using a piezo-device with room temperature water (~20-22°C) (W&H TIGON)

A2. Ultrasonic scaling using a magnetostrictive-device with room temperature water (~20-22°C) (DENTSPLY Cavitron)

or

B1. Ultrasonic scaling using a piezo-device with warm water Tigon + setting 3 (~36-37°C) (W&H TIGON)

B2. Ultrasonic scaling using a magnetostrictive-device with room temperature water (~20-22°C) (DENTSPLY Cavitron)

Study Procedure

Potential participants will be asked if they would be interested in taking part in the study during routine appointment visits. Interested participants will be provided with a research participant information sheet providing details of the study and invited to attend a screening appointment. During this appointment, the participant will have the chance to ask any questions they may have regarding the study. If the participant agrees to take part in the study, they will be asked to sign a consent form prior to any study procedures being undertaken. If the patient is suitable at the screening appointment the treatment appointment will follow on from the screening visit.

A dentally qualified clinician will record the participant's demographics, medical history, current/concomitant medications, perform an oral hard and soft tissue examination, and ensure the participant fulfils the inclusion and exclusion criteria for the study. Participants who successfully fulfill all the necessary entrance criteria will be randomised to receive supportive periodontal therapy according to the randomization schedule. Each treatment procedure will comprise of one treatment session for the whole mouth. For this study, to maintain blindness, the clinician will be responsible for randomisation, consent, screening and maintenance scaling (supportive periodontal therapy). To record the patient experience of discomfort, vibration and noise, the study co-ordinator/nurse will provide the participant with training in the use of a Visual Analogue Score VAS (Appendix 1+2). The participants will use this to record their experience following each part of their treatment using a VAS scale (Appendix 3).

A record will also be kept of the clinician's comparison of the two scalers at the end of the study with regards to ease of use, vibration and noise (Appendix 4).

STUDY POPULATION

Sufficient participants susceptible to periodontal disease in maintenance phase will be screened by the study site so that at least 140 participants who fulfil all entry criteria will be randomise to one of 4 groups, 35 each group.

STUDY DURATION

The study duration in total will be approximately 24 weeks, and for each participant the study will last about 60 minutes.

PARTICIPANT SCREENING

Voluntary written informed consent will be provided by all participants prior to any study procedures being performed. Those participants consenting to the study will then be screened by the study dentist. The participant will be provided with a copy of their signed and dated consent form and any other written information which they should be instructed to retain.

During the screening visit, the following evaluations will be performed by the same dentally qualified clinician:

- Demographics
- Medical History
- Current/Concomitant Medications
- Full Oral Soft Tissue (OST) examination including appropriate radiograph(s)
- Inclusion/Exclusion criteria

If, during a patient's participation in the trial, any new information becomes available that may affect the participants willingness to participate in the study, each ongoing participant will receive a copy of this new information and be re-consented into the study. Participants will be provided with a copy of the signed and dated amended consent form.

INCLUSION CRITERIA

1. Consent

Demonstrates understanding of the study and willingness to participate as evidenced by voluntary written informed consent and has received a signed and dated copy of the informed consent form.

2. Age

Aged at least 18 years.

3. Compliance

Understands and is willing, able and likely to comply with all study procedures and restrictions.

4. Susceptible to periodontal disease and have stability of the periodontium on examination (in supportive periodontal phase of treatment).

5. General Health

Good general health with (in the opinion of the investigator) no clinically significant and relevant abnormalities of medical history or oral examination.

EXCLUSION CRITERIA

1. Current or recurrent disease/dental pathology that could affect the assessments.

2. Current or relevant previous history of serious, severe or unstable physical or psychiatric illness, or any medical disorder that may require treatment or make the participant unlikely to fully complete the study, or any condition that presents undue risk from the study products or procedures.

3. Allergy/Intolerance

Known or suspected intolerance or hypersensitivity to the study materials (or closely related compounds) or any of their stated ingredients.

4. Participation in another clinical study or receipt of an investigational drug within 10 days of the screening visit.

5. Personnel

A member of the study site or a family relative. The study site for this protocol is the Clinical Trials Unit in the Bristol Dental School and Hospital and a Specialist Periodontal Practice. Employees of the sites are not eligible to participate.

6. Any participant who, in the judgement of the investigator, should not participate in the study.

Maintenance Phase

Maintenance phase supportive periodontal therapy includes reiterating oral hygiene with disclosing of plaque and instruction as necessary. At each treatment session, periodontal pockets will be recorded. If there is any plaque and tartar present on the patients' teeth, this will be removed. An ultrasonic irrigation of the gingival crevice of all teeth with an ultrasonic scaler will also be performed. The participant will be in the stable phase of periodontal management. The duration of this treatment will be approximately 30 minutes.

RANDOMISATION

Participants will be randomly allocated equally between the four groups A1, A2, B1 and B2, Table 1.

Table 1. Allocation of participants

Treatment Regimen	Right side (assessed second)	Left side (assessed first)
A1	Tigon+ room temperature water	Cavitron room temperature water
A2	Cavitron room temperature water	Tigon+ room temperature water
B1	Tigon+ warm water	Cavitron room temperature water
B2	Cavitron room temperature water	Tigon+ warm water

Supportive periodontal treatment will be performed on either side of the mouth using either the piezo or magnetostrictive scaler depending of the treatment regimen the participant is assigned to. In all participants, the left side of the mouth will always be assessed first for consistency.

STUDY SUPPLIES

1. Magnetostrictive Scaling Unit + tips
   Unit: Cavitron Select SPS Ultrasonic Scaler with Reservoir Pump
   Scaler tips: THINsert, FSI SlimLINE 10 left and FSI SlimLINE 10 right
   Supplier: Dentsply Sirona, Building 3, The Heights, Brooklands, Weybridge, Surrey KT13 0NY

2. Piezo Scaling Unit + tips
   Unit: Tigon +
   Scaler tips: 1P, 3PI, 3Pr
   Supplier: W&H, St Albans, Hertfordshire, AL2 2NJ

All equipment is marketed for use in the UK. The equipment will be used per the manufacturer's instructions and at the clinician's discretion for the best management of the patient. The tip inserts will be used as appropriate for each device and comparable tips have been chosen for each device. The irrigant (water) will be stored at room temperature and left in the room to achieve ambient temperature the day before the procedure (20-22°C).

The flow of irrigant will be standardized (37ml/minute for the Cavitron and setting 7 for the Tigon+) and a standard low volume aspirator will be used. The ultrasonics will be set on constant power settings rather than being able to vary power.

STATISTICAL ANALYSIS and STATISTICAL POWER

The study has two arms. In arm A, we compare Tigon room temperature (TR) vs. Cavitron room temperature cold (CR). This gives a within-subjects comparison. In arm B, we compare Tigon warm (TW) vs. Cavitron room temperature (CR). This likewise will give a within-subjects comparison. Participants will be randomly allocated equally between the four groups A1, A2, B1 and B2 (as per the randomisation schedule). The analysis for arm A compares halved differences between scores for the R side and those for the L side between groups A1 and A2. The analysis for arm B compares halved differences between scores for the R side and those for the L side between groups B1 and B2.

Each of these analyses will be run for each of 3 VAS scores representing pain/discomfort, noise and vibration, the primary analysis being the pain comparison TR vs. CR. The other 5 comparisons, involving noise or vibration and/or TW, will be classed as secondary. These split-unit analyses correspond closely to Hills & Armitage, 1979.

A total sample size of 140 participants will be recruited, with 35 subjects randomised to each of the 4 groups A1, A2, B1 and B2. With an estimated SD of 2.5, there is a power over 80% to detect a shift of 1 point of the mean pain / discomfort VAS score at a two-sided 5% alpha

level. This calculation corresponds to an analysis disregarding the paired nature of the data, and is therefore conservative.

REPORTING ADVERSE EVENTS AND SERIOUS ADVERSE EVENTS

All AEs will be reported from the time a signed and dated informed consent form is obtained until completion of the last study-related procedure. Those occurrences meeting the definition of SAEs must be reported using the UH Bristol Serious Adverse Event Form, including SAEs spontaneously reported to the Investigator within 30 days after the participant has completed the study (including post study follow-up). UH Bristol, on behalf of the Sponsor, will evaluate any safety information that is spontaneously reported by a CI beyond the time frame specified in the protocol.

All AEs, regardless of seriousness, severity, or presumed relationship to study treatments, must be recorded in the source document and the CRF, together with any measures taken. CIs must record in the CRF their opinion concerning the relationship of the adverse event to study therapy. UH Bristol, on behalf of the Sponsor, assumes responsibility for appropriate reporting of adverse events to the regulatory authorities.

- **Reporting Adverse events**

AEs will be recorded in the AE section of the CRF.

The investigator or designee must ask the participant the following question during each visit including any follow-up visits: **"Have you felt unwell, experienced any symptoms or taken any medication *(since your last visit) (today) (since your last dose) (since the last session)?"***

- **Reporting serious adverse events**

All SAEs must be reported to the UH Bristol contact (0117 3420233) by investigational staff within 24 hours of their knowledge of the event.

All SAEs that have not resolved by the end of the study, or that have not resolved upon discontinuation of the participant's participation in the study, must be followed until any of the following occurs:

- the event resolves
- the event stabilizes
- the event returns to baseline, if a baseline value is available

- the event can be attributed to agents other than the study drug or to factors unrelated to study conduct

- when it becomes unlikely that any additional information can be obtained (participant or health care practitioner refusal to provide additional information, lost to follow-up after demonstration of due diligence with follow-up efforts)

The death of a participant is considered an SAE, as is any event requiring hospitalization (or prolongation of hospitalization) that occurs during the course of a participant's participation. Exceptions to this are hospitalizations for:

- social reasons in absence of an adverse event

- the in-clinic protocol procedures

- surgery or procedure planned before entry into the study (must be documented in the CRF)

- **Follow-up of adverse events and serious adverse events**

After the initial report, the investigator is required to proactively follow up with each participant and provide further information on the participant's condition. All AEs/SAEs will be followed until resolution, until the condition stabilizes, until the event is otherwise explained, or until the participant is lost to follow-up. The investigator may be required to obtain additional laboratory tests or investigations, and/or provide the University of Bristol with additional documentation, including autopsy reports.

ETHICAL AND REGULATORY ASPECTS

Local Regulations/Declaration of Helsinki

The Chief Investigator will ensure that this study is conducted in full conformance with the laws and regulations of the country in which the research is conducted and the Declaration of Helsinki.

Informed Consent

It is the responsibility of the investigator, or designee, to obtain written (signed and dated by the participant) informed consent from each individual participating in this study. Major/substantial amendments to the protocol that affect the scope of the study at the participant level and/or updates to the safety profile of the investigational product (Investigator Brochure) should be reflected in the consent form and active participants re-consented.

Independent Ethics Committee

This study will be reviewed and given a favourable opinion by an independent Research Ethics Committee prior to any study procedures occurring. Any amendments will be reviewed by the Sponsor prior to submission for approval by the University of Bristol Faculty of Health Sciences Research Ethics Committee.

MONITORING OF THE STUDY

The University of Bristol has a policy for monitoring 10% of studies. Monitoring of studies is conducted in accordance with UH Bristol monitoring policy in relation to the service level agreement with the University of Bristol.

REFERENCES

1. N.J. Kassebaum et al. Prevention and Treatment of Periodontal Disease in Primary Care: Dental Clinical Guidance. http://www.sdcep.org.uk Global Burden of Severe Periodontitis in 1990-2010: A Systematic Review and Meta-regression. Journal of Dental Research, September 2014 DOI: 10.1177/0022034514552491.

2. Axelsson P & Lindhe J. The significance of maintenance care in the treatment of periodontal disease. Journal of Clinical Periodontology. 1981. 8: 281-294.

3. Ramfjord SP, Morrison EB, Burgett FG, et al. Oral hygiene and maintenance of periodontal support. J Periodontal. 1982. 53:26-30. SDCEP (2014).

4. Hojatollah Yousefimanesh, Maryam Robati, Mahdi Kadkhodazadeh, Reza Molla. A comparison of magnetostrictive and piezoelectric ultrasonic scaling devices: an *in vitro study.* J Periodontal Implant Sci. 2012 Dec; 42(6): 243–247. Published online 2012 Dec 31. doi: 10.5051/jpis.2012.42.6.243.

5. Chabanski MB, Gillam DG, Bulman JS, Newman HN. Prevalence of cervical dentine sensitivity in a population of patients referred to a specialist Periodontology Department. J Clin Periodontol. 1996 Nov;23(11):989-92.

6. Hills M, Armitage P, The two-period cross-over clinical trial, Br J Clin Pharmacol. 1979 Jul; 8(1): 7-20.

Appendix 1: Investigator/Designee Instructions for VAS Training Exercise –

Participants will be given instructions for using the VAS and asked to complete the VAS line scale training exercise form. The investigator or designee should read the instructions aloud while the participant reads along. Participants will be permitted to ask questions. However, most questions should be answered by rereading the appropriate section of the instructions. The investigator, or designee, will then determine whether the participant understands how to use the VAS based on the line scale training exercise answers and the criteria below.

Interpretation of the VAS Training Exercise

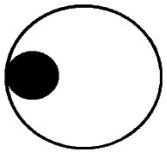
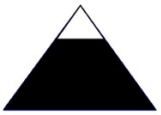
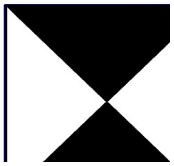
The objective of this exercise is not to determine whether the participant can get the exact answers, but to determine whether they understand the concept. Therefore, the following general criteria are suggested:

- Are the majority of the marks within ±10 mm of the correct value?
- Are the marks generally toward the correct side of the scale? In particular, is the first mark toward the left end, the second toward the right end and the third in the middle? Do the last three responses form a monotonically increasing sequence across the middle of the scale? Is item 4 ≥ item 1? Is item 5 ≥ item 8?

If participants appear unable to interpret the level of shading, the investigator or designee should talk them through the first three figures using questions such as, “is it more or less than half shaded?” and “is it a lot more or a lot less than half shaded?” If the marks are generally correctly ordered, but far from their true positions, the investigator or designee should try to get the participant to verbalize why they placed the marks as they did. However, the investigator or designee should be careful not to pressure the participant to change their responses. One approach would be for the investigator or designee to start with an item that the participant did well, ask about that and then continue by asking about one that seems off.

If participants are not able to deal with the concept of proportions as presented in the exercise, it is unlikely that they will provide useful responses on the subjective and clinical response questionnaires. These participants should be disqualified.

Answer Key

No Shading — Complete Shading		10
No Shading — Complete Shading		90
No Shading — Complete Shading		50
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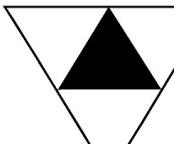
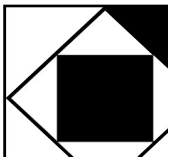
No Shading — Complete Shading		75
No Shading — Complete Shading		25
No Shading — Complete Shading		38
No Shading — Complete Shading		67

Appendix 2: Participant Instructions for VAS Training Exercise

We will be asking you to rate your oral health using a line scale such as the one below. You should respond by making a single vertical mark on the line.

NO PAIN _____ WORST PAIN IMAGINABLE

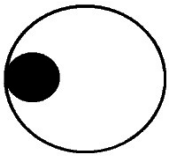
If you experience no pain or discomfort, you should make your mark at the left end of the line ("No Pain"). If you couldn't imagine the pain being any worse, you should make your mark at the right end of the line ("Worst Pain Imaginable"). If your discomfort pain falls somewhere between these two extremes, you should mark a point on the line that represents how bad the pain is relative to these to end-points. If you think that it is half-way between No Pain and the Worst Pain Imaginable, then you would mark the middle of the line.

When we test your teeth, it is important to distinguish between sensation ("I feel something") and discomfort or pain ("It hurts"). A sensation that does not hurt should be rated as "No pain."

In all the evaluations, there are no right or wrong answers; only your opinion counts. Answer carefully, but keep in mind that first impressions are often the most accurate.

In order to give you some practice with this scale, we would like you to complete the exercise on the next page. In this exercise you will be estimating how much of the total area of a series of shapes has been shaded. If none of the figure has been shaded, you should mark the left end of the line. If the figure has been completely shaded, you should mark the right end of the line. If only part of the figure has been shaded, you should make a vertical mark at the appropriate point on the line. For example, if half of the figure has been shaded, you should make your mark in middle of the line. If a quarter of the figure has been shaded, you should make your mark one quarter of the distance from the left end of the scale, etc. Please remember, we are asking you to estimate the area shaded and then to estimate the position of your mark on the line.

Please make a single vertical mark at the point on the line that best represents the degree to which the figure is shaded.

No Shading ——— Complete Shading	
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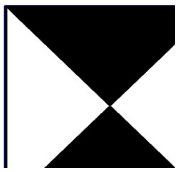
No Shading ——— Complete Shading	
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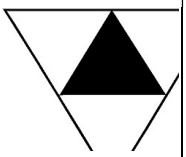
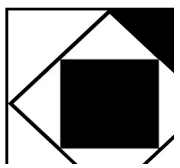
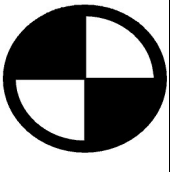
No Shading ——— Complete Shading	
No Shading ——— Complete Shading	
No Shading ——— Complete Shading	

Appendix 3 –Post- supportive periodontal therapy Questionnaire

To be completed following supportive periodontal therapy by the patient for each side of the mouth treated

Left side 1 ____ (*Please add treatment (randomisation) code for each side of mouth treated)*

Right side 2 ____

Please indicate how much PAIN/DISCOMFORT you experienced during your supportive periodontal therapy (0 is no pain, 10 is maximum pain)	NO PAIN 0 ——— WORST PAIN IMAGINABLE 10
Please indicate how much NOISE you experienced during your supportive periodontal therapy (0 is no pain, 10 is maximum pain)	NO NOISE 0 ——— WORST NOISE IMAGINABLE 10
Please indicate how much VIBRATION you experienced during your supportive periodontal therapy (0 is no pain, 10 is maximum pain)	NO VIBRATION 0 ——— WORST VIBRATION IMAGINABLE 10
Do you have any comments about the surgery?	
Which treatment did you prefer? (Please circle your answer)	**Right side** **Left side** **No preference**

Appendix 4 – Clinician's View of 2 scalers

Tigon ____ *(Please complete a separate form for each scaler, indicating with a 'X' which instrument is being reviewed)*

Cavitron ____

Ease of use of scaler (0 is Easy, 10 is Hard)	EASY ——— HARD 0 10
Vibration of scaler during use (0 is no vibration, 10 is worst vibration)	NO VIBRATION ——— WORST VIBRATION 0 10
Noise of scaler during use (0 is no noise, 10 is worst noise)	NO NOISE ——— WORST NOISE 0 10
Do you have any comments about the scaler?	
Which instrument do you prefer (Please circle your answer)	Tigon Cavitron