

MT211 VibraTip for testing vibration perception to detect diabetic peripheral neuropathy

National Institute for Health and Care Excellence

Medical Technologies Evaluation Programme

MT211 VibraTip for testing vibration perception to detect diabetic peripheral neuropathy

Consultation Comments table

MTAC date: 17 October 2014

There were 27 consultation comments from 21 consultees (16 NHS professionals, 1 manufacturer, 1 EU healthcare professional, 1 DH representative, 1 professional organisation and 1 EAC representative). The comments are reproduced in full.

Com . no.	Consultee number and organisation	Sec. no.	Comments	Response
1	6 EAC representative	Section 1.1 Provisional recommendations	<p>The provisional guidance states ‘Although VibraTip appears to be easy to use, portable and reliable in its functionality....’</p> <p>It is uncertain whether the device is capable of delivering a repeatable stimulus over its lifetime (see study by Horsfield &amp; Levy, 2013), and it is also unclear to what extent the variability of the stimulus affects diagnostic accuracy (for example see section 2.3.2, page 21, of EAC assessment report). If this particular use of “reliable” in the draft guidance incorporates “repeatable”, then it is misleading.</p>	<p>Thank you for your comment.</p> <p>The Committee considered this comment and felt their original statement that VibraTip “appears....reliable” accurately reflected their views and would not be misleading.</p> <p>Section 4.7 has been updated to refer to the uncertainties about the impact of the battery life on the repeatability of the test.</p>
2	21 Sponsor	Section 1.1 Provisional recommendations	<p>In the Guidance overview, immediately prior to making provisional recommendations, NICE states:</p> <p>" ...The medical technology guidance on VibraTip recommends further research. This recommendation is not intended to preclude the use of the technology in the NHS but to identify</p>	<p>Thank you for your comment.</p> <p>The explanatory text on research recommendations was developed by NICE, and is added to all medical technologies guidance with research recommendations to help the reader understand the context of the Committee’s recommendations. The text is not intended to be customized for different</p>

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			<p>further evidence which, after evaluation, could support a recommendation for wider adoption."</p> <p>However, recommendation 1.1 includes the wording: "...more evidence is needed...to support the case for its routine adoption in the NHS."</p> <p>The vast majority of routine foot examinations for diabetic peripheral neuropathy are undertaken in a primary care setting as part of the GMS contract and QOF and we question whether the NICE wording above <b>will</b> (paradoxically) <b>preclude</b> any use of the technology in this setting, even though the current use of VibraTip conforms with QOF below.</p> <p>The very latest framework guidance for GMS contract 2014/5 (NHS England Gateway reference:01264) includes DM indicator 012 (NICE 2010 menu ID: NM13) which calls for patients with diabetes to undergo a foot examination and risk classification. The DM 012 Rationale states:</p> <p>"The foot inspection and assessment includes: identifying the presence of sensory neuropathy (loss of ability to feel a monofilament, vibration or sharp touch) and/or the abnormal build-up of callus.."</p> <p>We would maintain that there is already much ambiguity in the guidance available on foot</p>	<p>technologies.</p>

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			<p>screening for patients with diabetes. Although different tests and methods may be advocated and debated by specialists, surely improved patient care relies on more neuropathies being detected earlier and patient education being introduced to help prevent foot damage. Diabetes UK (in conjunction with the Association of British Clinical Diabetologists, Scottish Diabetes - Foot Action Group, Diabetes Inpatient Specialist Nurses UK Group, Foot in Diabetes UK, NHS Diabetes, Primary Care Diabetes Society, The Society of Chiropodists and Podiatrists, Training Research and Education for Nurses in Diabetes, the Welsh Endocrine and Diabetes Society) have recently developed a footcare pathway for people with diabetes as part of their Putting Feet First campaign. VibraTip conforms with this pathway which simply states "Test foot sensations using 10g monofilament or vibration; palpate foot pulses; etc"</p> <p>Although NICE states that their recommendation is not intended to preclude the use of VibraTip, we believe that the current wording could lead to exactly the opposite in practice. Therefore we suggest a slight change to the wording in the overview as follows:</p> <p>" ...The medical technology guidance on VibraTip recommends further research. This recommendation is not intended to preclude the existing use of the technology in the NHS (e.g. for QOF purposes) but to identify further evidence which, after evaluation, could support a recommendation for wider adoption."</p>	

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3	6 EAC representative	Cost evidence Section 5.2	<p>'These values did not influence the base case results because the costs were identical for both arms.'</p> <p>Costs of consequences in this type of model are often the same; in fact the issue with this model was the transitional probabilities were the same in each arm, not the costs (see section 4.2.2, page 84, of EAC assessment report).</p>	<p>Thank you for your comment.</p> <p>The text in section 5.2 has been changed to clarify that both the costs and transitional probabilities were identical for both arms.</p>
4	6 EAC representative	Cost evidence Section 5.8	<p>In this paragraph, please consider noting that the EAC's revised per examination estimates for the 10g monofilament were based on lifetime data from a published technical study (Lavery et al. 2012).</p>	<p>Thank you for your comment.</p> <p>The text in section 5.8 has been changed to clarify that the EAC's revised estimates were based on lifetime data from a published study.</p>
5	21 sponsor	Cost Considerations 5.8 & 5.10	<p>The External Assessment Centre have based their per-examination cost of £0.076 for a Baileys 10g monofilament on a data table from:</p> <p>Lavery LA, Lavery DE, Lavery DC et al. (2012) Accuracy and durability of Semmes-Weinstein monofilaments: what is the useful service life? Diabetes Research &amp; Clinical Practice 97: 399–404.</p> <p>EAC's conclusion that a monofilament is within acceptable range for 2,000 cycles, hence 200 patients, conflicts with the authors conclusions of: "At best, monofilaments starting at the accepted 10 +/- 1g buckling force would remain within a usable range (9-11g) for 7-9 days or to evaluate 70-90 patients."</p> <p>The data table demonstrates a out-of-range mean buckling force prior to 2,000 cycles (at 1,400 cycles) - however this has been explained as a</p>	<p>Thank you for your comment. The EAC has confirmed the original analysis remains accurate:</p> <p>The EAC has also confirmed that it did not dismiss any data from the Lavery et al. paper as a 'blip' (this word was not used in the EAC assessment report).</p> <p>The sensitivity analyses on costs, presented in Table 4.5 of the EAC assessment report include the lower value of 800 uses from Lavery et. al (2012).</p> <p>The EAC considers that an estimate of 2000 uses (200 patients) is the best estimate of <i>practicable</i> useful lifetime for the monofilament from the data provided by Lavery et al. This is from the mean values reported in Table 1, excluding the slightly outlying value at 1400 uses. The theoretical lifetime value of 804 uses, calculated from lab-based experimental data using a fitted exponential model, was not considered as the most realistic value in a clinical setting, and this judgement was backed by reference to the Bailey monofilament Instructions for Use card insert, which states: 'For optimum</p>

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			'blip' by EAC. However, Fig 1 in the same paper clearly demonstrates that the 1,400 cycle plot is not an isolated blip and that significant out-of-range results are recorded after only 800 cycles. This suggests why the authors, being very close to the datasets, have reached their conclusion. Per-examination cost of the monofilament based on the data and conclusions of the study authors will be significantly higher (i.e. £0.17-£0.22) than those used by EAC. On this basis, an economic case for VibraTip would be clearly demonstrated.	<p>performance, it is recommended that the Bailey monofilament should be replaced every six months if used on multiple patients on a daily basis and every twenty-four months when used on a more occasional basis'.</p> <p>In preparing its Assessment Report (EAC Correspondence Log, Question 4, page 3 of 29, MTCD <a href="#">supporting documents</a>), the EAC asked the sponsor about the comparable useful lifetime of Vibratip but no specific threshold was stated.</p>
6	6 EAC representative	Committee considerations 5.12	The document states 'The Committee concluded that further modelling of the economic case was essential.'. However, the specific recommendation for further economic modelling is not reflected in recommendation 1.2.	<p>Thank you for your comment.</p> <p>Section 1.2 includes the following recommendation The research should gather information on the health system and economic impact of introducing VibraTip for detection of diabetic peripheral neuropathy. This should include longer term outcomes so that an accurate and comprehensive cost consequences analysis can be carried out.”</p> <p>Any future cost consequences analysis would include detailed modelling.</p> <p>The Committee felt that economic modelling would be clearly understood to be included in a cost consequence analysis and agreed to leave the wording as it stands.</p>
7	1 NHS Professional (physician)	general	I am writing to strongly support the use of Vibratip in screening for diabetic foot problems in the UK. Firstly, let me say that I have no commercial interest in this whatsoever and although I am the senior author of a paper which tested the Vibratip, we received no financial support for this study which was done independently.	<p>Thank you for your comment.</p> <p>The EAC explored the issue of the NHS potentially benefitting from sales of VibraTip in detail and its report to the Committee is available <a href="#">here</a>. It concluded there would be a negligible impact on the cost case.</p>

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			<p>It was my group, originally in 1983 (Boulton et al, Diabetes Care 1983; 6: 26-33) that first showed the relationship between vibration and active foot ulcers and subsequently we confirmed with the prospective study that those diabetic patients with no history of foot ulcers who had abnormal vibration perception threshold using a biothesiometer, had a 7-fold annual increased risk of ulceration compared to non-neuropathic patients (Young MJ et al, Diabetes Care 1994; 17: 557-560). Subsequent to that we have done a lot of research in this area and published a large number of papers on risk factors for diabetic foot ulcers. In the 1999 publication (Reiber GE, Diabetes Care 1999) we published on pathways to foot ulceration confirming that neuropathy was the most important contributory factor in the genesis of foot ulcers in diabetic patients both in the USA and the UK.</p> <p>In our recent paper confirming the usefulness of the Vibratip in screening for patients at high risk of foot ulcers, we showed excellent correlation between the Vibratip and all the other standard tests including the Ipswich Touch Test, the biothesiometer, Neuropathy Disability Score, monofilament, etc, (Bowling FL et al, Diabetic Medicine 2012; 12: 1550-1552).</p> <p>In the same issue of Diabetic Medicine, our colleagues from Nottingham (Game and Jeffcoate) in a not dissimilar paper, also showed the usefulness of this device.</p> <p>The advantage of the Vibratip over all the other</p>	

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			<p>methods apart from the biothesiometer, is that it involves a forced choice mechanism therefore increasing its reliability as a screening tool. This is a cheap disposable device that was developed by a colleague and it has a patent held by the NHS such that any profits from the sale of this cheap and efficacious device will be channelled back into the National Health Service. The Vibratip is already being used across the world and again sales internationally will help the NHS.</p> <p>I have no hesitation in strongly recommending to NICE that this be adopted as a simple, effective and accurate screening tool for identifying the high risk foot in diabetes.</p>	
8	2 NHS Professional (diabetes specialist podiatrist)	general	<p>I had been using Vibratip for approximately one year as my neurothesiometer had been condemned and no replacement had been granted until recently.</p> <p>I loved the VibraTip, found it a very useful tool, and of course a lot easier to transport compared to the Neurothesiometer.</p> <p>It would be great if VibraTip was recommended in NICE guidelines.</p>	<p>Thank you for your comment.</p> <p>The Committee carefully considered whether to change the guidance in response to this and other comments from NHS professionals. It decided that the comments were anecdotal but did give confidence in the Committee's view that the device shows promise.</p>
9	3 NHS Professional	general	<p>For a long time I have been concerned that practice nurses who invariably do the periodic diabetic assessments have been getting inaccurate or inconsistent results using a tuning fork to assess vibration sense. The vibratip is such an inexpensive and totally efficient innovation that it deserves to completely replace the dated tuning fork method. I think the device is marvellous.</p>	<p>Thank you for your comment.</p> <p>The Committee carefully considered whether to change the guidance in response to this and other comments from NHS professionals. It decided that the comments were anecdotal but did give confidence in the Committee's view that the device shows promise.</p>

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10	4 EU healthcare professional (physician)	general	<p>I am using the Vibratip device for detection of diabetic peripheral neuropathy (DPN) with great enthusiasm in daily clinical practice as I find it very precise and handy. The utilization in the clinical team has doubled as this device is so rapid and handy compared to the graduated tuning fork or even the monofilament.</p> <p>I am currently the leader of the Swiss diabetic foot working group and associated to a study of detection of diabetic peripheral neuropathy and risk of diabetic foot ulceration in diabetic patients and we have chosen the Vibratip as the our main device besides the graduate tuning fork. Please let me know if I can contribute anything else to your current evaluation of the Vibratip.</p>	<p>Thank you for your comment.</p> <p>The Committee carefully considered whether to change the guidance in response to this and other comments from NHS professionals. It decided that the comments were anecdotal but did give confidence in the Committee's view that the device shows promise.</p>
11	5 NHS Professional (SpR Diabetes and Endocrinology )	general	<p>I just want to highlight a few points with regards to <b>'Vibratip'</b>.</p> <ol style="list-style-type: none"> <li>1. I have used this device for more than a year now to check for peripheral neuropathy in my patients with diabetes. I must say it is a very good device and it's as sensitive (if not more) as the 10g monofilament.</li> <li>2. Its easier to keep clean</li> <li>3. It has a long battery life.</li> <li>4. It is more user friendly</li> <li>5. Patients find it more tolerable than the monofilament</li> </ol> <p>This device is well used by my other registrar colleagues who also find it very useful. Thanks.</p>	<p>Thank you for your comment.</p> <p>The Committee carefully considered whether to change the guidance in response to this and other comments from NHS professionals. It decided that the comments were anecdotal but did give confidence in the Committee's view that the device shows promise.</p>
12	7 NHS	General	<p>I have personally used it in my clinical practice and have found vibratip a very useful tool for the</p>	<p>Thank you for your comment.</p> <p>The Committee carefully considered whether to</p>



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	Professional (Consultant Endocrinology / Diabetes & Acute Medicine)		assessment of diabetic peripheral neuropathy. It is a small, easy to keep in my pocket / bag and yet very efficient tool. I endorse it fully.	change the guidance in response to this and other comments from NHS professionals. It decided that the comments were anecdotal but did give confidence in the Committee's view that the device shows promise.
13	8 NHS Professional	General	I have found VibraTip an excellent toll and recommend it highly.	Thank you for your comment. The Committee carefully considered whether to change the guidance in response to this and other comments from NHS professionals. It decided that the comments were anecdotal but did give confidence in the Committee's view that the device shows promise.
14	9 NHS Professional	general	We have been using Vibratip for our Diabetic checks for sometime and it works perfectly and lasts ages.  I'd thoroughly recommend this and all credit should be given to the creator.	Thank you for your comment. The Committee carefully considered whether to change the guidance in response to this and other comments from NHS professionals. It decided that the comments were anecdotal but did give confidence in the Committee's view that the device shows promise.
15	10 NHS Professional	general	Dear NICE team I have used the VibraTip and evaluated its accuracy in diagnosing diabetic peripheral neuropathy as my research project which was recently published on the British Journal of Diabetes and Vascular Disease. I found this devise user friendly and also easier to use compared to the tuning fork. Interpretation of results were easy and therefore had better utility in comparison to other devices.	Thank you for your comment. The Committee carefully considered whether to change the guidance in response to this and other comments from NHS professionals. It decided that the comments were anecdotal but did give confidence in the Committee's view that the device shows promise.

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			I am currently training doctors in the use of this device and believe it will roll out nationally.	
16	11 NHS Professional	general	I have used Vibratip on diabetic patients for several years. I have found it useful and more accurate than a tuning fork which is dependant on the users ability touse corectly. However the vibratip is expensive if used a single patient use .	Thank you for your comment. The Committee carefully considered whether to change the guidance in response to this and other comments from NHS professionals. It decided that the comments were anecdotal but did give confidence in the Committee's view that the device shows promise.
17	12 NHS Professional	general	The vibratip is real advance in clinical diagnostic utility	Thank you for your comment. The Committee carefully considered whether to change the guidance in response to this and other comments from NHS professionals. It decided that the comments were anecdotal but did give confidence in the Committee's view that the device shows promise.
18	13 NHS Professional (Specialist Podiatrist)	general	I am a Specialist Podiatrist with 12 post graduate experience.  I assess patients daily and I have been using the Vibra tip since 2011. I find it easy to use, non-invasive, hygienic, very inexpensive and very reliable even with repeated usage.  From a clinical point of view if a patient can not feel the vibration from this tool then I use a neurothesiometer. It would be very interesting to know what the Vibatip corresponds with the VTP (neurothesiometer)	Thank you for your comment. The Committee carefully considered whether to change the guidance in response to this and other comments from NHS professionals. It decided that the comments were anecdotal but did give confidence in the Committee's view that the device shows promise.

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			From a screening point of view this tool is ideal and I shall continue to use it alongside my neurothesiometer, 10 gram monofilament, eyes and hands for a clinical assessment.	
19	13 NHS Professional (Specialist Podiatrist)	general	I would be happy to consider further research with this product if required.	Thank you for your comment. The Committee carefully considered whether to change the guidance in response to this and other comments from NHS professionals. It decided that the comments were anecdotal but did give confidence in the Committee's view that the device shows promise.
20	14 NHS Professional (Consultant Neurologist)	general	I have been using vibra tipi for about 2 yrs now instead of a tuning fork in neurology outpatients. I find it incredibly useful and far more reliable than a tuning fork	Thank you for your comment. The Committee carefully considered whether to change the guidance in response to this and other comments from NHS professionals. It decided that the comments were anecdotal but did give confidence in the Committee's view that the device shows promise.
21	16 NHS Professional	general	I'm an endocrine specialist registrar. I have used vibratip for diabetic peripheral neuropathy for 3 years. Along side 10g monofilament, it offers good sensitivity and specificity in peripheral neuropathy related to diabetes. Ease of use is the main factor. Easy to clean, easy for patients to follow instructions and reproducible.	Thank you for your comment. The Committee carefully considered whether to change the guidance in response to this and other comments from NHS professionals. It decided that the comments were anecdotal but did give confidence in the Committee's view that the device shows promise.
22	15 NHS Professional	general	I have used these devices for approximately 5 years and found them to be an excellent method of testing vibration sense in patients with suspect peripheral neuropathy. The device is long lasting	Thank you for your comment. The Committee carefully considered whether to change the guidance in response to this and other

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	(Consultant Podiatric Surgeon)		and is easily wiped clean after use. (I have no links with the manufacturer.) I hope you find these comments helpful	comments from NHS professionals. It decided that the comments were anecdotal but did give confidence in the Committee's view that the device shows promise.
23	17 NHS Professional (GP)	general	Sorry have not done an audit but it picked up +ve & -ve areas of skin sensation to vibration in a much quicker and reliable way than the tuning fork (128Hz) - especially useful in emergency/urgent referrals to Foot Clinic where hours can make a difference. The Vibratip gives prolonged constant freq/y vibrations but the tuning fork quickly wanes	Thank you for your comment.  The Committee carefully considered whether to change the guidance in response to this and other comments from NHS professionals. It decided that the comments were anecdotal but did give confidence in the Committee's view that the device shows promise.
24	18 Professional Healthcare Organisation (Diabetes Foot Podiatry Clinical Research Fellow)	general	FDUK would like it to be noted that we welcome the chance to comment on this project. We recognise that screening and detecting loss of sensation is essential in order to risk stratify diabetes patients into appropriate programmes of education and management. Therefore we are supportive and welcome innovation in the development and promotion of a specific new tool to detect loss of sensation. However, the response from the FDUK Board has highlighted some reservations: <ul style="list-style-type: none"> <li>1. Primarily among them is the risk that this very process may restrict the assessment of neuropathy by non-specialists as these practitioners may not have access to the device.</li> <li>2. There is a risk that many primary care IT systems are linked to the current quality outcome framework and record traditional measures of neuropathy such as loss of protective sensation via 10g monofilament</li> </ul>	Thank you for your comment.

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			<p>or loss of vibration (usually in practice via a calibrated tuning fork) and as such it is unlikely to be embedded into general practice unless it is linked with the QOF and practice computers are upgraded. This would have additional cost issues.</p> <p>3. While it has been shown that the Vibratip is not inferior to the 10g monofilament in clinical practice, it has not been shown that it is any superior. The Board commented that the 10g monofilament has been well researched and identified as the most effective tool currently and it is cheap and reliable. Therefore, they could not fully support the adoption of this tool unless it can be demonstrated that it is superior in these categories. However, there are well known complications with the use of monofilaments in terms of the reliability when they are overused in a single session and also when they are old and have lost their tensile strength. It is recognised that Vibratip may demonstrate the on-going or continuous effective use, as opposed to what a monofilament/tuning fork may provide. Cost effectiveness (linked to battery life) needs further rigorous comparison with established modalities (monofilament and tuning fork).</p> <p>We have some concerns about the detection of neuropathy by loss of vibration only to diagnose diabetic peripheral neuropathy. NICE need to be absolutely clear about the purpose of the device in the clinical context.</p>	

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25	18 Professional Organisation (Diabetes Foot Podiatry Clinical Research Fellow)	general	FDUK do not understand why there were there no Podiatrists on the NICE Committee (podiatrists being key clinicians involved in developing and organising foot screening programmes). They would have added expertise and a deeper understanding of the clinical practice, equipment and service requirements.	Thank you for your comment. The membership of the NICE Medical Technology Advisory Committee is described in " <a href="#">MTAC Terms of reference and standing orders</a> ", NICE always recruits external Expert Advisers to support the Committee and the External Assessment Centre in the assessment of a medical technology. For VibraTip, the Committee has received advice from 3 podiatrists, one of whom is part of the evaluation 'lead team'.
26	18 Professional Organisation (Diabetes Foot Podiatry Clinical Research Fellow)	general	We (FDUK) recommend that further comparative high quality research is conducted and published, prior to Vibratip being considering as an alternative to 10g monofilament or calibrated 128mhz tuning fork, as part of NHS diabetes foot screening or neuropathy (loss of sensation) assessment. Without this, as previously clarified, we cannot promote this as the recommended device for detecting loss of sensation. It should not be excluded entirely and Vibratip may have some benefit with some groups who have difficulty in communicating. One member has done several sessions with Deaf Diabetes UK and residential care and found it comfortable/easy to communicate. However, it is recognised that this is a minority but is still a beneficial addition to the tool kit.	Thank you for your comment. The MTEP methods guide (section 8.2.3) states "a [research] recommendation is not intended to preclude the use of the technology in the NHS but to identify further evidence which, after evaluation, could support a recommendation for wider adoption."
27	18 Professional Organisation (Diabetes Foot Podiatry Clinical	general	FDUK has significant concerns that this guidance is running in parallel to the review of guideline CG10 diabetic foot care with no apparent cross referencing between the two groups, can we be assured that the guidance from the two groups will be consistent?	Thank you for your comment. Section 8.4.1 of the <a href="#">Clinical Guidelines manual</a> describes the process for ensuring consistent guidance.

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28	19 Healthcare Professional	general	As a practice nurse specialising in diabetes I was introduced to the vibratip by one of the local community endocrinologists to aid our foot assessments on diabetic patients. Having been trained by podiatrists to undertake diabetic foot assessments and previously used the tuning fork I have found the vibratip to be much more accurate at assessing neuropathy and am glad that the practice I work at supports the use of this device. The gadget is easy to order and lasts a long time if looked after. The company quickly replaced one which wasn't working when received without any hesitation.	Thank you for your comment.
29	20 DH representative	general	I wish to confirm that the Department of Health has no substantive comments to make, regarding this consultation.	Thank you for your comment.
30	21 sponsor	General Cost Issue, Royalties	<p>Although apparently rejected by the EAC and the Committee, we maintain that VibraTip-related royalty payments to the NHS should be a cost consideration.</p> <p>The device was invented within the NHS by an NHS employee, was developed &amp; patented by an NHS Trust and is therefore owned, not by the sponsor but, by the NHS. Royalty income from worldwide sales could potentially more than offset the total acquisition cost of VibraTips in NHS and even though this royalty is directed to a single Trust, it will still largely benefit patient care within the NHS organisation.</p>	<p>Thank you for your comment.</p> <p>The EAC explored this issue in detail and its report to the Committee is available <a href="#">here</a>. It concluded there would be a negligible impact on the cost case.</p>

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*"Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or Advisory committees."*