

# NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

## Centre for Health Technology Evaluation

### Review Decision

#### **Review of MTG22: VibraTip for testing vibration perception to detect diabetic peripheral neuropathy**

This guidance was issued in December 2014.

NICE proposes an update of published guidance if the evidence base or clinical environment has changed to an extent that is likely to have a material effect on the recommendations in the existing guidance.

#### **1. Review decision**

Transfer the guidance to the 'static guidance list'.

Consult on the review proposal

#### **2. Original objective of guidance**

To assess the case for adoption of VibraTip for testing vibration perception to detect diabetic peripheral neuropathy.

#### **3. Current guidance**

1.1 *VibraTip shows potential to improve the detection of diabetic peripheral neuropathy and to provide cost savings to the NHS. VibraTip appears to be easy to use, portable and reliable in its functionality, but the current evidence does not support the case for its routine adoption in the NHS. Therefore, research is recommended to address uncertainties in the potential benefits to patients and the NHS of using VibraTip. Research is needed into the diagnostic accuracy of VibraTip compared with the 10 g monofilament and calibrated tuning fork in the diagnosis of peripheral neuropathy in people with diabetes. This research should also address the assessment of vibration perception compared with touch sensation in this clinical context. NICE will update this guidance when substantive new evidence becomes available.*

## 4. Rationale

No new evidence has been identified which is likely to change the existing research recommendations. The clinical pathway has not changed. There is still potential benefit for the use of VibraTip, however, the uncertainties around the effectiveness of the technology have not been addressed. There is no change in the cost of VibraTip or the comparator technologies.

## 5. New evidence

The search strategy from the original assessment report was re-run. Relevant references from April 2014 onwards were reviewed. Additional searches of clinical trials registries were also carried out and relevant guidance from NICE and other professional bodies was reviewed to determine whether there have been any changes to the care pathways. The company was asked to submit all new literature references relevant to their technology along with updated costs and details of any changes to the technology itself or the CE marked indication for use for their technology. The results of the literature search are discussed in the 'Summary of evidence and implications for review' section below. See Appendix 2 for further details of ongoing and unpublished studies.

### 5.1 Technology availability and changes

VibraTip is available to the NHS and is technically unchanged. The CE mark is unchanged. The cost for VibraTip is the same as reported in MTG22.

### 5.2 Clinical practice

The relevant NICE pathway is foot care for people with diabetes. The clinical guideline is NG19 [Diabetic foot problems: prevention and management](#) which was last updated in January 2016. There have been no significant changes to the care pathway. NG19 recommended foot inspection of adults with diabetes using a 10 g monofilament at least annually.

People with suspected diabetic neuropathy are still tested with either the 128Hz tuning fork, 10g monofilament or a neurothesiometer.

Five experts gave advice on the review. One expert was aware of routine use of VibraTip at an NHS site. An expert who is also a co-investigator in Azzopardi et al (2018) which compared VibraTip, neurothesiometer, and 128Hz tuning fork stated, [REDACTED]

### 5.3 NICE facilitated research

KiTEC EAC published a research protocol developed as a result of MTEP research commissioning (Goddard et al, 2018). The protocol was designed to answer uncertainties in the effectiveness of VibraTip by comparing it, a neurothesiometer, and 10g monofilament against nerve conduction velocity measurements as a gold standard in people with diabetes. However, this research study was not funded, despite two applications by the External Assessment Centre (Guy's and St Thomas' Charity and Diabetes UK). The [protocol](#) is available for researchers to use, and it has been cited (Raymond et al, 2019). NICE do not fund clinical research arising from the Medical Technologies Evaluation Programme; NICE do fund protocol development and other research facilitation activities.

Since the GE meeting on 8 January 2019, 2 experts have provided NICE with critical reviews of Goddard et al (2018). One expert stated:

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■

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The other expert stated:

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Neither expert commented on the likelihood of the study being funded despite being asked. In the opinion of the technical lead, such a response during grant review would mean that funding was not awarded.

### 5.4 New studies

The literature searches identified 3 relevant studies which included VibraTip as an intervention. None of the new studies provided evidence which addressed the research recommendations in the original guidance.

Azzopardi et al (2018) reported a multi-centre cross-sectional study (n = 100, mean age 72.8 years) comparing 3 technologies for the assessment of vibration detection in diabetic neuropathy tests in Malta. No gold standard was employed to quantify diabetic neuropathy. Cramer's V test showed small to moderate association between VibraTip, neurothesiometer and 128Hz tuning fork. In the same group of 100 people, 12 % were insensitive to vibration from the 128 Hz tuning fork versus 21% for a neurothesiometer and 28.5% for VibraTip (p<0.001). This was a negative finding for VibraTip. The discussion suggested that if only one screening test was used to assess vibration detection, it was likely to yield high false negative results. In the absence of a

gold standard, the study did not answer the research recommendations in MTG22.

Gómez-Banoy et al (2017) was a cross-sectional study using Neuropad, VibraTip, and 10 g monofilament to test elderly people with type II diabetes (mean age = 70.8 years, n = 93). 19 people (8.7%) presented an abnormal result with VibraTip yet the proportion of people with neuropathy using the Michigan Neuropathy Screening Instrument (MNSI) was 54.2% ( $p < 0.05$ ). The results for VibraTip are: sensitivity = 54.2%, specificity = 91.3%, positive predictive value = 68.4%, negative predictive value = 85.1%. The study was conducted in Colombia.

Lasca et al (2016) was a prospective case control study involving 90 people and which compared 10g monofilament, 128Hz tuning fork, and VibraTip. Diagnostic accuracy results from the study for VibraTip were sensitivity = 76.7%, specificity = 77.5%, positive predictive value = 62.9%, and negative predictive value = 87.1%. The study was conducted in Romania.

## **6. Summary of new information and implications for review**

The new evidence does not address the uncertainties in the existing guidance and so the research recommendation is still valid. Research facilitation activities by NICE resulted in a protocol from KiTEC EAC (Goddard et al, 2018) which was designed to address the research recommendations. KiTEC were unsuccessful in two grant applications based on the protocol. Had the study been funded, KiTEC would have done the research.

## **7. Implications for other guidance producing programmes**

None.

## **8. Implementation**

NICE did not develop any adoption resources for MTG22. The adoption and impact team was unable to identify any data on use or uptake of the product.

## **9. Equality issues**

No equalities issues were identified in the guidance. No new equalities issues have been identified.

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## Appendix 1 – explanation of options

If the published Medical Technologies Guidance needs updating NICE must select one of the options in the table below:

Options	Consequences	Selected – ‘Yes/No’
Amend the guidance and consult on the review proposal	The guidance is amended but the factual changes proposed have no material effect on the recommendations.	No
Amend the guidance and do not consult on the review proposal	The guidance is amended but the factual changes proposed have no material effect on the recommendations.	No
Standard update of the guidance	A standard update of the Medical Technologies Guidance will be planned into NICE’s work programme.	No
Update of the guidance within another piece of NICE guidance	The guidance is updated according to the processes and timetable of that programme.	No

If the published Medical Technologies Guidance does not need updating NICE must select one of the options in the table below:

Options	Consequences	Selected – ‘Yes/No’
Transfer the guidance to the ‘static guidance list’	The guidance remains valid and is designated as static guidance. Literature searches are carried out every 5 years to check whether any of the Medical Technologies Guidance on the static list should be flagged for review.	Yes
Defer the decision to review the guidance	NICE will reconsider whether a review is necessary at the specified date.	No
Withdraw the guidance	The Medical Technologies Guidance is no longer valid and is withdrawn.	No

## Appendix 2 – supporting information

### Relevant Institute work

#### *Published*

None identified.

#### *In progress*

None identified.

### Registered and unpublished trials

Trial name and registration number	Details
A Study to Evaluate the Performance of VibraTip by Different Clinical Users <a href="https://www.clinicaltrials.gov/ct2/show/study/NCT01878682">NCT01878682</a>	<p>The study aims to evaluate the accuracy of the VibraTip device compared to the Gold Standard, the 10g Semmes Weinstein Monofilament (MF) Test, and the accuracy and usability of the VibraTip® device, as measured by different community medical practitioners.</p> <p>The study was reported to be “not yet recruiting” in 2013 and there has been no update. No relevant studies were identified from the investigator (Dr E Jude).</p>

## Appendix 3 – changes to guidance

No changes are proposed to the original guidance.

### References

Azzopardi K, Gatt A, Chockalingam N et al. (2018) Hidden dangers revealed by misdiagnosed diabetic neuropathy: A comparison of simple clinical tests for the screening of vibration perception threshold at primary care level. *Primary Care Diabetes* 12 (2): 111-115.

Goddard K, Vas P, Purves A, McMillan V, Langford T, Reid F, Edmonds M (2018) Comparing the diagnostic accuracy of simple tests to screen for diabetic peripheral neuropathy: Protocol for a cross-sectional study. *JMIR Res. Protoc.* 7(4):e72. doi: 10.2196/resprot.7438.

Gómez-Banoy N, Cuevas V., Soler F. et al. (2017) Screening tests for distal symmetrical polyneuropathy in Latin American patients with type 2 diabetes mellitus. *Archives of Endocrinology and Metabolism* 61 (5): 470-475.

Lasca M, Taut AL, and Veresiu IA (2016) Comparative evaluation of several simple screening tests for risk of neuropathic ulcerations of feet in patients with diabetes mellitus. *Romanian Journal of Diabetes, Nutrition and Metabolic Diseases* 23 (1): 67-72.

Raymond B, Steriovski J, Gillyard K, Yang C, Wu SC, Crews RT (2019) Choosing a vibratory test to pair with Semmes Weinstein monofilament testing for evaluating lower extremity sensation in patients with diabetes: a comparison of three vibratory methodologies. *Journal of Diabetes Science and Technology*  
<https://journals.sagepub.com/doi/10.1177/1932296819849478>



## Consultation Comments table

Com. no.	Consultee number and organisation	Sec. no.	Comments	Response
1	1 National Institute for Health and Care Excellence		<p>The surveillance team agrees with the proposal to transfer this guidance to the static list.</p> <p>We considered MTG22 in our recent surveillance review of NG19 – diabetic foot problems. Our impact assessment is below:</p> <p><b>Potential future effect on recommendations</b></p> <p>MTG22 states that the VibraTip shows potential to improve the detection of diabetic peripheral neuropathy however evidence was lacking to support its routine adoption in the NHS. Further evidence was required comparing VibraTip to either a calibrated tuning fork or 10 g monofilament. NG19 currently recommends 10 g monofilament testing for diabetic peripheral neuropathy (recommendation 1.3.4). If substantial new evidence is found to support the routine adoption of VibraTip, as stated in MTG22, there may be an impact on the recommendations of NG19.</p> <p>We did not include testing for peripheral neuropathy in our searches for NG19 as we focussed specifically on wound dressings and wound healing. We did not receive any comments from stakeholders during consultation regarding MTG22 or VibraTip. We did however receive several comments about NeuroPad-MTG38.</p>	Thank you for your comment.

Com. no.	Consultee number and organisation	Sec. no.	Comments	Response
2	2 National Institute for Health and Care Excellence		Thank you for including us in this review. We note your suggested changes and have no comments to make. We did not develop an adoption resource for this guidance.	Thank you for your comment.
3	2 National Institute for Health and Care Excellence		The only active topic we are aware of in this clinical area is Neuropad which published in September 2018	Thank you for your comment.

*"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."*

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