

Point-Of-Care Diagnosis & Monitoring of Peripheral Neuropathy

Tamas Hickish, Neil Vaughan, Venky Dubey,
Jonathan Cole, Peter Thomas, Sharon Docherty, BU

Derek Kelly, NHS Innovations South West Ltd



Wall Street Journal, Jan 2015.

Dr. Eric Topol; cardiologist, director of the Scripps Translational Science Institute in La Jolla, Calif, author of “The Patient Will See You Now: The Future of Medicine Is in Your Hands,” consults for Google, AT&T, Walgreens, Quanttus and Sotera Wireless.

Hospitals’ rooms on their way out; so are their labs.

Smartphone attachments will soon measure;

Blood electrolytes; liver, kidney and thyroid function; analysis of breath, sweat and urine.

X ray

Ultrasound

Hand-held MRI

O₂/NO for asthma attack

Wallace Schwam, Jan 14, 2015

I can hardly wait for my standard App. to refer me to a specialist App. providing, of course, that my Health Insurance App. agrees in advance.

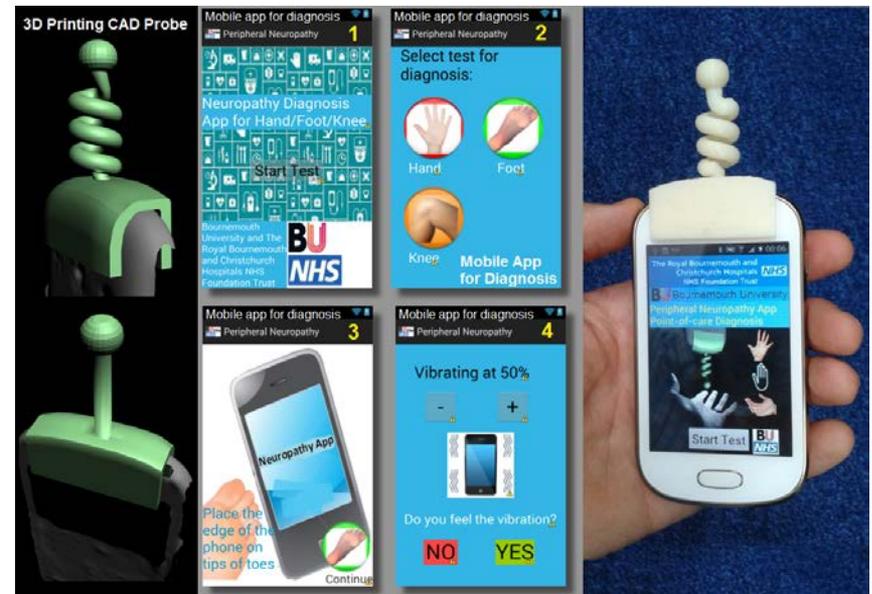
If this doesn't happen in a timely manner, my legal App. may get involved.

Peripheral Neuropathy...

- Causes numbness, pain and weakness in limbs
- Affects 2.4% of the population (8.0% over 65)
- Seen in 66% of type 1 diabetes patients, 59% of type 2
- Commonly occurs in people suffering from cancer or diabetes, two of the most common diseases worldwide
- Rates are higher in third world countries due to leprosy, HIV, diabetes and toxins

POC Peripheral Neuropathy Device

- Smartphone device
 - 3D-printed probe
 - Uses smartphone vibration motor
 - Smartphone app
 - Uses GPS, Wi-Fi
- Wireless data transmission
- Encryption and cybersecurity will be designed-in
- Patent applied for



Device Use

- Point of care evaluation of vibration perception – an indicator of nerve function

Step 1: Probe applied to region of interest



Step 2: Level of vibration perception recorded.



Step 3: Wi-fi & Bluetooth Data Transmission.



Improved Health Outcomes

- Enables patients to self-monitor at home without the need to travel to hospital for neuropathy assessment
- Innovates care pathways for patients receiving potentially neurotoxic chemotherapy
- Encourages patient engagement in managing their disease e.g. diabetes
- Allows more frequent monitoring for earlier detection of sensation loss, before irreversible damage occurs

Value for Money

- Reduces need for patients to visit hospital for neuropathy assessment, freeing up health care professionals' time
- Potential to prevent / minimise neuropathy
- Probe is cheap to manufacture and disposable
- Revenue generation from commercial exploitation of device



Institution of Engineering & Technology (IET) Innovation award in London (2015, November). The device was shortlisted in the top 4 from entries in 93 counties in 3 separate categories.



The IET Innovation Awards 2015

This is to certify that
Bournemouth University, Royal Bournemouth and Christchurch Hospital
NHS Foundation Trust and Poole Hospital NHS Foundation Trust
are awarded

Highly Commended

in the **Measurement in Action** category
of the IET Innovation
Awards 2015

18 November 2015

Nigel Fine
IET Chief Executive and Secretary

Naomi Climer
IET President

www.theiet.org/innovation



The IET Innovation Awards 2015

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Christchurch Hospital NHS Foundation Trust
and Poole Hospital NHS Foundation Trust
are awarded

Highly Commended

in the **Communications** category
of the IET Innovation
Awards 2015

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The IET Innovation Awards 2015

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are awarded

Highly Commended

in the **Healthcare Technologies** category
of the IET Innovation
Awards 2015

18 November 2015

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IET Chief Executive and Secretary

Naomi Climer
IET President

www.theiet.org/innovation

Healthcare Technologies

Salurate salivary test for pre-eclampsia

Morgan Innovation and Technology Ltd

Salurate is a highly innovative technology which utilises a unique way of testing for pre-eclampsia.



It uses samples of saliva to test for uric acid levels and is therefore a non-invasive, pain and needle free test which allows pregnant women to test themselves in the comfort of their own home.

Professor Tamas Hickish Winner of NHS Innovation Challenge Prize

BUCRU Co-Director Professor Tamas Hickish, and Dr Venky Dubey and Dr Neil Vaughan from the BU Faculty of Science and Technology are winners of an NHS Innovation Challenge Prize in the Acorn Open Innovation category. Their innovation is a new mobile device to detect neuropathy in patients undergoing cancer treatment. The team collected their £10,000 prize to develop their innovation further at an event at Anglia Ruskin University on 28 January.



Congratulations to Professor Hickish and the rest of the team!

Using the Acorn Challenge Prize

- £10k will be used to:
- 3D print a batch of probes for clinical trials
- Conduct a clinical trial in patients receiving chemotherapy to optimise the device & gather ‘proof of principle’ data
 - Test the user interface
 - Evaluate the patient experience
 - Compare against hospital neurothesiometers and neurophysiology
- Enable the next stage of commercialisation

Utility, Sterility, Disposability

VibraTip™ has been specifically designed to overcome the limitations of tuning forks for testing the integrity of vibration sense in clinic and by the bedside. With sufficient battery life for several months of routine use,

VibraTip™ is easily wiped clean and small enough to be concealed in the hand. Its silent switch and quiet operation minimizes cueing and its rounded head allows vibration sense to be assessed specifically and rapidly from almost any angle.



NICE National Institute for Health and Care Excellence

VibraTip for testing vibration perception to detect
diabetic peripheral neuropathy

Issued: December 2014 last modified: March 2015

NICE medical technology guidance 22

guidance.nice.org.uk/mtg22



6 Conclusions

6.1 The Committee concluded that VibraTip is a promising technology with the potential to have a positive impact on the diagnosis of diabetic peripheral neuropathy. However, the Committee considered that more evidence was needed on VibraTip's diagnostic performance compared with the 10 g monofilament and calibrated tuning fork. The Committee recommended that a high quality diagnostic accuracy study comparing VibraTip with the 10 g monofilament and the calibrated tuning fork is needed to establish the comparative clinical benefits of the technologies, and also address the speed and ease of use of the devices. The data from this research, together with updated economic modelling, will enable the review of the current recommendations.

Andrew Dillon
Chief Executive
December 2014



ASSIGNMENT

BETWEEN

PROFESSOR J.D. COLE

AND

BU INNOVATIONS LIMITED

D Young & Co LLP

120 Holborn

London

EC1N 2DY

PARTIES

Professor J.D. Cole, c/o 2nd Floor Melbury House, 1-3 Oxford Road, Bournemouth, BH8 8ES (“**Assignor**”)

BU Innovations Limited of 2nd Floor Melbury House, 1-3 Oxford Road, Bournemouth, BH8 8ES (the “**Assignee**”).

BACKGROUND

The Assignor and Bournemouth University have collaborated on a project to develop a diagnostic device and associated software, and have agreed that the Assignee, which is a subsidiary of Bournemouth University Higher Education Corporation, is the proprietor of the Patent Application as defined below. The Assignor has agreed to assign any and all rights it may have in the Patent Application to the Assignee on the terms set out in this assignment.

AGREED TERMS

INTERPRETATION

The definition in this clause applies in this assignment:

The Patent Application: UK patent application number 1508513.7

ASSIGNMENT

In consideration of the sum of £1 (receipt of which the Assignor expressly acknowledges), the Assignor hereby assigns to the Assignee, absolutely with full title guarantee, in Great Britain and throughout the world, any and all proprietary rights, title and interest in and to the Patent Application, and in and to all and any inventions (and future improvements) disclosed in the Patent Application, including the right to claim priority from and to prosecute and obtain grant of patents; the right to file divisional applications based thereon; and the right to prosecute and obtain grant of patents on each and any such divisional application.

The Assignor hereby assigns their rights to bring, make, oppose, defend, and appeal proceedings, claims or actions, and obtain relief (and to retain any damages recovered), in respect of any infringement, or any other cause of action arising from the Patent Application, and any subsequent patents that may be granted pursuant to the Patent Application.

FURTHER ASSURANCE

The Assignor shall, at the Assignee's expense, perform all further acts and things, and execute and deliver all further documents, required by law or which the Assignee requests to vest in the Assignee the full benefit of the right, title and interest in any and all rights assigned to the Assignee under this assignment, and to perfect any registered title to such interests, patents or patent application, with any patent office anywhere in the world.

VARIATION

No variation of this assignment shall be effective unless it is in writing and signed by the parties (or their authorised representatives).

SEVERANCE

If any provision or part-provision of this assignment is or becomes invalid, illegal or unenforceable, it shall be deemed modified to the minimum extent necessary to make it valid, legal and enforceable. If such modification is not possible, the relevant provision or part-provision shall be deemed deleted. Any modification to or deletion of a provision or part-provision under this clause shall not affect the validity and enforceability of the rest of this assignment.

THIRD PARTY RIGHTS

No one other than a party to this assignment shall have any right to enforce any of its terms.

GOVERNING LAW

This assignment and any dispute or claim arising out of or in connection with it or its subject matter or formation (including non-contractual disputes or claims) shall be governed by and construed in accordance with the law of England and Wales.

JURISDICTION

Each party irrevocably agrees that the courts of England and Wales shall have exclusive jurisdiction to settle any dispute or claim arising out of or in connection with this assignment or its subject matter or formation (including non-contractual disputes or claims).

This document takes effect on the date of the signature of the final party to date the assignment.

Tim Brodie
Bournemouth University Higher Education
Corporation
Melbury House
1-3 Oxford Road
Bournemouth
Dorset
BH6 8ES

Our Ref: P106653PCT NMM GSJ

16 May 2016

New International Patent Application No. PCT/GB2016/051405
Corresponding to United Kingdom Application No. 1508513.7
"Neuropathy Assessment Device"
BU Innovations Limited & Bournemouth University Higher Education Corporation

Dear Tim

Following your instruction, I am pleased to confirm that we have filed an International (PCT) patent application on 16 May 2016 claiming the above priority, which has been allocated PCT application number: PCT/GB2016/051405. Please find enclosed copies of the application papers as filed, together with the on-line filing receipt. Please check to confirm that details such as the applicants, inventors and any priority claim are correct.

We should receive the International search report for this application within a few months, although these are occasionally delayed. The application will be published on or shortly after 18 months from the priority date.

In the majority of the designated territories the deadline for national processing under Chapter I PCT is now 30 months from the priority date, i.e., 18 November 2017.

Chapter II processing may still however be required if the Applicant wishes to respond to the International Search Report and Written Opinion and amend the PCT application centrally. **The deadline for filing a Demand for the purposes of central amendment is (i) 3 months from the date that the Written Opinion (ISA) is issued, or (ii) 22 months from the priority date, whichever date is the later.** We will advise you of the relevant date when reporting the Written Opinion (ISA) and International Search Report. If following this route we recommend that the response to the Written Opinion (ISA) and proposed amendments be filed at the same time as the Demand.

I discussed the content of the UK combined search and examination report with the main inventor Neil Vaughan in a telephone call on 5 May 2016, and we explored various options for distinguishing over the two citations "Hasbun" and "Vicendese".

In the end we concluded that we were very comfortable that distinction can be made over both of these documents and moreover that on balance it would be preferable to not amend the claims of this new PCT application before filing. The two main reasons for this. Firstly by keeping the claims in their current format (i.e. matching the UK application) the scope of the search performed for this PCT application will correspond to that of the UK application and not be any narrower. We can therefore have more confidence that any potentially related documents will be found and we can then address any issues they raise. Secondly by keeping the PCT claims same as the UK claims,

and due to the fact that we have another year before response to the UK combined search and examination report is due, it is probable that the results of the PCT search will be available before that UK response is due, and therefore we can coordinate the response to each, and will be more efficient and cost-effective.

Neil and I also briefly discussed the development of this invention as a commercial product and he told me that progress is being made towards a clinical trial and also with regards to commercialisation. In this context I would like to remind you about the possibility of applying for a registered design for the product. As you may well be aware, a registered design protects the shape and look of a product (as opposed to a patent which protects the underlying technological function), and once a final form of the product has been developed, this could be very useful and relatively cheap way of establishing further protection for this product and valuable IP for Bournemouth University. However, as you may also be aware, a registered design must be filed within 12 months of having publicly disclosed the design (in the UK or EU, which allow such a grace period, although not all countries do). Accordingly, I would strongly recommend tracking when a relatively final version of the device is made public, and bearing in mind that the publication of the UK patent application (expected to be in mid-November this year) will itself be such a public disclosure. Please do not hesitate to contact me if you would like further information about filing such a registered design application.

We will keep you informed of the progress of the application and in the meantime in the meantime our pending invoice is being sent to Clare Frampton and Deborah Wakely for their review and approval.

Yours sincerely
for D Young & Co LLP



Dr Nicholas Malden
Partner
nmm@dyoung.com

Enc: Copy of Application Papers as Filed
Copy of On-line Filing Receipt
Invoice

Electronic Filing Receipt

Acknowledgement of receipt

We hereby acknowledge receipt of your request for the processing of an international application according to the Patent Cooperation Treaty as follows:

Submission number	1200194269	
PCT application number	PCT/GB2016/051405	
Date of receipt	16 May 2016	
Receiving Office	Intellectual Property Office, Newport	
Your reference	P106653PCT	
Applicant	BU Innovations Limited	
Number of applicants	2	
Country	GB	
Title	A DEVICE, SYSTEM AND METHOD FOR VIBRATION SENSITIVITY ASSESSMENT	
Documents submitted	eolf-plda.xml eolf-appb.xml eolf-vlog.xml eolf-abst.txt eolf-othd-000002.pdf (4 p.)	eolf-requ.xml eolf-fees.xml eolf-othd-000001.pdf (24 p.) eolf-appb-P000001.pdf (12 p.) eolf-othd-000003.pdf (4 p.)
Submitted by	CN=Nicholas Malden 21918	
Method of submission	Online	
Date and time receipt generated	16 May 2016, 13:15:51 (BST)	
Digest	1F:EC:14:F3:F2:11:2F:FF:1F:41:6E:8F:49:D9:69:B2:40:DA:88:AD	

/Intellectual Property Office, Newport/

Conclusions

1. Point of Care testing of neuropathy would have huge health benefit, perhaps most of all in the target group of our study, those undergoing neurotoxic chemotherapy.
2. Our device allows testing and communication of results and resulting changes in medication.
3. Further support is needed for extensive clinical trials.
4. The idea and development of the device to a working model was relatively straightforward. Proper clinical trials and protection of copyright have proved more involved.