Gmail Steve Hardaker <viamed.steve.hardaker@gmail.com>

Fwd: SoR? TOF

1 message

LEE, Peter (SHERWOOD FOREST HOSPITALS NHS FOUNDATION TRUST) <peter.lee3@nhs.net> 23 September 2021 at 10:48
To: "COGGON, Mandy (SHERWOOD FOREST HOSPITALS NHS FOUNDATION TRUST)" <mandy.coggon@nhs.net>, "GLADMAN, Danielle (SHERWOOD FOREST HOSPITALS NHS FOUNDATION TRUST)" <danielle.gladman@nhs.net>, "WRIGHT, Tina (SHERWOOD FOREST HOSPITALS NHS FOUNDATION TRUST)" <tina.wright4@nhs.net>
Cc: "steve.hardaker@viamed.co.uk" <steve.hardaker@viamed.co.uk>, "FLETCHER, Stephen (SHERWOOD FOREST HOSPITALS NHS FOUNDATION TRUST)" <stephen.fletcher2@nhs.net>

Hi Steve

As shared 1-1 yesterday with you in response to your update, our Educators (Mandy/Danielle cc'ed in) we will need support on introducing these into clinical use, ideally face-face, if you could kindly get back to us all ASAP, that would be useful

Kind regards

Peter D. Lee C.Eng MIET MIPEM

Consultant Head, Clinical Engineering Services & Trust Medical Device Safety Officer

Incorporating Medical Equipment Management Department (Memd)

Diagnostics and Outpatients Division

Kings Mill Hospital

Sherwood Forest NHS Foundation Trust

Mansfield Road

Sutton-in-Ashfield

NG17 4JL

01623 622515 x 3882

Please visit our websites on the following link http://sfhnet.nnotts.nhs.uk/memd/default.aspx or to report routine repairs http://sfh-ram/maintenance5000/mainmenu.aspx?Guest=True

Our mission ....Maximizing the availability of safe medical devices for your patients...Choosing it right- and using it right - will keep it right!

Service Registered with BSi continuously to Iso9001 Quality Management Standard since 1990

Begin forwarded message:

> **From:** "Steve Hardaker" <office@viamed.co.uk>
> **To:** "LEE, Peter (SHERWOOD FOREST HOSPITALS NHS FOUNDATION TRUST)" <peter.lee3@nhs.net>
> **Subject: Re: SoR?**

Hi Peter,

I've tracked the package and can see that it has now arrived at the Trust this morning, so hopefully the device has been passed to you by now.

With regards to a talk-through of the device, unfortunately, that's not something that I am able to do, having not had hands-on experience with it myself.

I've spoken to my Director, who has done manufacturer product training, and he is able to speak to the Clinical Educator if needed, however, the information provided should provide enough information to allow clinically trained staff to set up and operate the device.

One of the mandates of the MDR is that *the instructions for use shall be appropriate to the particular device, its intended purpose and the technical knowledge, experience, education or training of the intended user(s)*. As this device is intended for use by clinically trained users, if the materials that the manufacturer has provided are not sufficient to allow an understanding of the device and to develop internal competency and training materials, we really need to identify where the shortfalls are and ask the manufacturer to improve and clarify the instructions.

I have attached the key documents that the Clinical Educator will require, can I ask that these are forwarded on with a suggestion that they work through the materials and identify where points of clarification are required?

Please pass on my email address and, if the Clinical Educator is able to advise me of any queries, we can provide answers where we have them or forward the comments to the manufacturer where we do not, thus ensuring that we obtain the manufacturer's response, as opposed to Viamed's interpretation as an intermediary distributor.

I apologise that this is a departure from the way that things were done in the past with company representatives being able to train clinical users directly, but we are being steered away from that model by increasingly stringent regulatory standards.

Regards,

Steve Hardaker
Technical Support Manager
Viamed Ltd.
Please note: Viamed is enacting a coronavirus contingency plan to allow sales and admin staff to work from home, and I am now working remotely. Telephone calls to the main office will be answered remotely, but please continue to use email where possible.

Website: www.viamed.co.uk
email: steve.hardaker@viamed.co.uk
Tel: +44 (0)1535 634542
Fax: +44 (0)1535 635582

On Tue, 21 Sept 2021 at 16:16, LEE, Peter (SHERWOOD FOREST HOSPITALS NHS FOUNDATION TRUST) <peter.lee3@nhs.net> wrote:

> Hi Steve
>
> Just a note that the SoR has yet to turn up
>
> Given that the ITU educator will have to create an internal competency and like staff, will be new to this device, would you be able to do at least a MS Teams-based talk through of the device now, I know last time we spoke that you hadn't had a chance yourself to start gaining more familiarity with?
>
> Kind regards
>
> Peter D. Lee C.Eng MIET MIPEM
>
> Consultant Head, Clinical Engineering Services & Trust Medical Device Safety Officer
> Incorporating Medical Equipment Management Department (Memd)
> Diagnostics and Outpatients Division
> Kings Mill Hospital
> Sherwood Forest NHS Foundation Trust
> Mansfield Road
> Sutton-in-Ashfield
> NG17 4JL
>
> 01623 622515 x 3882
>
> Please visit our websites on the following link http://sfhnet.nnotts.nhs.uk/memd/default.aspx or to report routine repairs http://sfh-ram/maintenance5000/mainmenu.aspx?Guest=True
>
> Our mission ....Maximizing the availability of safe medical devices for your patients...Choosing it right- and using it right - will keep it right!
>
> Service Registered with BSi continuously to Iso9001 Quality Management Standard since 1990
>
> **********
> ********** **********
>
> This message may contain confidential information. If you are not the intended recipient please:
> i) inform the sender that you have received the message in error before deleting it; and
> ii) do not disclose, copy or distribute information in this e-mail or take any action in relation to its content (to do so is strictly prohibited and may be unlawful).
> Thank you for your co-operation.
>
> NHSmail is the secure email, collaboration and directory service available for all NHS staff in England. NHSmail is approved for exchanging patient data and other sensitive information with NHSmail and other accredited email services.
>
> For more information and to find out how you can switch visit Joining NHSmail – NHSmail Support

3 attachments

Instruction Manual TOF3D.pdf
1410K

TOF3D Neuromuscular Transmission Monitor User Training Quick Guide.pdf
2088K

Leaflet - TOF3D Nuromuscular Transmission Monitor.pdf
3075K