



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

Re: SoR? TOF

1 message

Steve Hardaker <steve.hardaker@viamed.co.uk>

23 September 2021 at 11:58

Reply-To: steve.hardaker@viamed.co.uk

To: "LEE, Peter (SHERWOOD FOREST HOSPITALS NHS FOUNDATION TRUST)" <peter.lee3@nhs.net>

Cc: "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>, "FLETCHER, Stephen (SHERWOOD FOREST HOSPITALS NHS FOUNDATION TRUST)" <stephen.fletcher2@nhs.net>, Steve Nixon <steve.nixon@viamed.co.uk>

Good afternoon all,

I've just spoken with Peter, who has been very helpful in explaining the training requirements of the Trust, and we are looking to arrange an MS Teams meeting for next week to go through an overview of the device.

From Viamed's end, I need to determine the availability of my Director colleague, Steve Nixon, so if I can ask what days/times are available for the Clinical Educators and interested parties, we can look for a suitable window to schedule this.

Provisionally can I ask for your availability on weekdays between 9:30am and 2:00pm, with the expectation that an hour should offer sufficient time?

With regards to the depth of information that we can provide: I have to clarify that Viamed staff are not clinically trained or fully conversant with current ITU and Theatre practices beyond a good general understanding. That said, we should be able to familiarise you with the device, and this will give you the opportunity to present any specific questions, which we can forward to the manufacturer (MIPM) for clarification if we cannot answer them directly.

The Instructions For Use and User Training Quick Guide were attached to the original email from Peter, and an additional resource in the form of a Windows-based interactive software simulator is available from our website using the link below:

http://www.viamed.co.uk/library/sim/TOF_3Dv1.0.exe

I look forward to hearing from you and, if you have any immediate questions in the meantime, please feel free to ask.

Regards,

Steve Hardaker
Technical Support Manager
Viamed Ltd.

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On Thu, 23 Sept 2021 at 11:49, LEE, Peter (SHERWOOD FOREST HOSPITALS NHS FOUNDATION TRUST) <peter.lee3@nhs.net> wrote:

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)

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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.

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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
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