Gmail Main Account <viamedinbox@gmail.com>

Fwd: NHS PAQ questionnaires

1 message

Steve Nixon <office@viamed.co.uk> 23 September 2021 at 13:19
Reply-To: steve.nixon@viamed.co.uk
To: Sales <Sales@mipm.com>

Hi Marc

Thanks for the update, please see added notes below in red text.

Is it possible to date or add a version number to presentations. The quick quide looks identical to one previously supplied, but the file sizing is different; we could do with a quick way of verifying that we have the up-to-date versions of presentations...

Steve

---------- Forwarded message ---------
From: **Sales** <Sales@mipm.com>
Date: Wed, 22 Sept 2021 at 15:41
Subject: AW: NHS PAQ questionnaires
To: steve.nixon@viamed.co.uk <steve.nixon@viamed.co.uk>

Hi Steve,

Please find attached the answers below.

If you have any further questions, do not hesitate to contact me.

Best regards

Marc Stoye

Marketing & Sales

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Von: Main Account <viamedinbox@gmail.com> **Im Auftrag von** Steve Nixon
Gesendet: Donnerstag, 16. September 2021 11:27
An: Sales <Sales@mipm.com>
Cc: Gunnar Bida <Gunnar.Bida@mipm.com>
Betreff: NHS PAQ questionnaires

Hi Marc

As previously discussed, for sales to the UK NHS we have to complete questionnaires (PAQ) prior to hospitals purchasing equipment. We have done this for the MIPM TOF3D and we just have the following queries to resolve. The main one is that we must have at least one NHS recognized cleaning agent.

The following are the remaining issues from the PAQ Form that we need answers to (our comments are asterisked):

- 4c - What is the recommended working lifetime for this Device?
* We have put 7 years as a nominal value as it coincides with the 7 years support period (so we are not saying the device lifespan is longer than we can support it), can you please provide MIPM's view on this.

Our expected working lifetime is 8 years. OK good

- 6a - Has a protocol for post-delivery inspection and acceptance testing of Device function and safety been attached to this Form ?
* This is a basic QA procedure performed by a Clinical Engineer to ensure that the device is operating correctly before putting into service. It does not necessarily have to be a full QA procedure, more of a check to ensure that the device is working, undamaged and all parts are present and correct.

Unfortunately we do not have any acceptance testing for the customer. We are testing the devices before we ship them according to the attachment “FB_TSC_TOF3D_V1.1.pdf”.

We guarantee that the product is functional when it is delivered. If the customer does not believe us, you can request the technical safety check for the customer and I will send it to you.

OK we will try and devise one as the hospitals are quite insistent. Also, they are querying how to carry out a functional test? The IFU states to carry this out, for example see the warnings on pages 8 and 9.

Always perform functional check before using device.

A function test must be carried out before using this device.

- 7b - Does the manufacturer or an authorised servicing agent provide a maintenance / repair and technical support service ?
- if YES, then have details of all service contract options been detailed, fully costed and attached to this Form ?
* We can provide a service options / costings document? In order to do this we need the costings for the main PCB assembly. Do you have any MIPM service support programmes?

You can basically only replace defective casing parts. The display is glued to the circuit board. If one of the two is defective, then the entire unit has to be replaced.

Please find attached the safety check protocol.

OK, but what is the part number and price of the PCB assembly?

- 11a - Is competency-based user training available from the manufacturer or an authorised provider ?
* At the moment we have said no, we could prepare this but under the regulations I'm not sure that we are not allowed to do this. Do you have nay materials for end user training and assessment? Of course we will carry out the training.

Since you have participated in the TOF3D training you are allowed to train the users.

Please find attached our customer training presentation.

OK we will work with this

Of course we can carry out training. As afar as we are aware, the MDR states that userss should be suitably qualifiesd and should be able to use the device by following the IFU. We can show them how to operate the device and demonstare the features, but we are now not allowed to offer comments regarding clinical apsects.

I would ask if you can reword the stanetn on page 7 of the IFU:

WARNING: The TOF3D must only be used by qualified and trained medical staff. In order to be trained, please contact MIPM or an authorized representative.

This suggests that we carry out all the training! For example one of the current prospects is for 4 units for an ICU, possibly more for operating theatres (The competition is Draeger). In the ICU there are 90 members of staff to train, the logistics and expense of us continually doing this is not feasible.

A better statement would be:

WARNING: The TOF3D must only be used by qualified and medically trained staff.

If additional device training materials are required, please contact MIPM or an authorized representative.

This way we can train the trainers.

PAQ2 6b - Please provide specific detail of the plastics used in all rigid external surfaces.

We need this for all the materials including the keypad and LCD window.

PAQ2 Q6a: All the equipment requires generalised cleaning on a regular basis and must be compatible with 3 of the products we use. Can the equipment be cleaned using:

A: Clinell Universal Sanitising Wipes
B: Peracetic Acid Reagents
C: Chlorine Releasing Agents
D: Hydrogen Peroxide Vapour 4.9% (Deprox)
E: Ultra Violet Decontamination

* They have stated 3 types. we would be happy if we can just confirm Clinell.

Further to emails with Gunnar, I have arranged to send some samples of cleaning materials.

Steve

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Steve

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6 attachments

image002.png
2K

image004.jpg
3K

image006.png
3K

PM_TOF3D_E_V1.0.pdf
466K

FB_TSC_TOF3D_V1.1.pdf
103K

TOF3D_Customer Training_EN.pdf
2331K