

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

3:40 PM (20
hours ago)

to John, john.lamb

Hi John,

Please see the following folder in your T drive:

T:\John Lamb\From Steve H\TT480(RO)

I have copied a number of emails and call logs regarding the development of the reduced outlet Tom Thumb, which was developed at the request of Dr Sam Oddie, Consultant Neonatologist at Bradford Royal Infirmary in 2004-5.

At that time, I demonstrated a Tom Thumb TT480 infant resuscitator at BRI and allowed them to trial it. The trial went well but they already use Fisher & Paykel Neopuff infant resuscitators in the Trust and concerns were raised over having two different patient circuits that are not compatible with each other's parent devices.

At the time we did not have an adapter to accomplish this, so Dr Oddie requested that we supply a number of Tom Thumb TT480 with a 10 mm O.D. outlet to allow them to use their pre-existing supply of Fisher & Paykel Neopuff infant resuscitation circuits. Initially, he requested a 'dual outlet' that was stepped with a 15 mm O.D. connection stepping down to a 10 mm I.D. connection to allow the use of either circuit. We felt that this would add potential confusion, so on 31st March 2005 I emailed Dr Oddie to state that we are developing a 10 mm outlet but if he wants to do a written risk assessment, we would supply a dual outlet version for that purpose. He declined this and opted for the single 10 mm outlet.

John, you spoke to Doug McIvor at the MHRA and we emailed them at least twice to ask about any relevant standards that may need to be applied, I have located the incoming and outgoing emails.

I obtained 2 examples of the Neopuff patient circuit, which have a 10 mm I.D. connector, and these were used to test the Tom Thumb for both physical fit and to determine whether there was any adverse affect on performance.

I was not involved in the physical testing and I do not know if it was documented in writing but I do know that the Tom Thumb performed exactly as expected with the Neopuff circuit, which is why we moved forward with it. Kevin Rush was involved on the Regulatory Affairs side of this project at the time, I am not sure who did the testing, there may be something archived.

The 10 mm Outlet was given the part number 0330295. A TT480 with the 10 mm outlet attached was given the part number 0310080 and the model TT480(RO), designating the reduced outlet. A TT490-15 with the 10 mm outlet attached was given the part number 0310082, however, none of this variant were ever manufactured.

BRI purchased 12x 0310080 Tom Thumb Infant Resuscitator (RO) on 9/8/2005.

In March 2009, BRI ordered 2 more 0310080 TT480(RO), however, the outlets were custom-made so would have meant weeks of delay, so they agreed to accept standard TT480, for which they would use the newly introduced Intersurgical 10 mm resuscitation circuit that comes with adapters to fit either the Tom Thumb, Neopuff or other manufacturer's devices.

On 23/5/2009, Medical Physics at BRI contacted us to say that they wanted to convert the 2 recently received TT480s to have 10 mm outlets to allow them to use the Intersurgical circuit without adapters, we sent 2x 0330295 10 mm outlets free of charge.

In February 2015, BRI ordered 16x 0310080 TT480(RO) as all of their original units were written off due to oil contamination in an air pipeline. We did not have this model in stock, so we supplied 16x 0310030 TT480 (standard configuration with 15mm outlet) and they asked for the 10 mm outlets to modify them in-house. We supplied 8x 0330295 free of charge, which is all of the stock we had. They did not request us to make any more of the outlets, presumably they either re-used some of the old outlets or are using adapters for the Intersurgical circuit.

Aside from BRI, the only other customer that has had the 0330080 variant is Medical Essentials on 27/9/12.

I see no need to continue this reduced outlet variant Tom Thumb as there are now alternative solutions available to Bradford Royal by using their current patient circuits with an adapter.

Regards,

Steve