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Marketing Job Logger - Marketing Job Logger

**NeoFlow Leaflet**

Issue ID #60132

Date Created 30/Jun/2015

Issued To: Derek Lamb

Completed Status: Still Outstanding

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Notes:

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04 Aug 2015 Catrin Hird

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06 Aug 2015 Catrin Hird  
Job 241

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06 Aug 2015 Steve Hardaker

Next Action Changed From 38 To Steve Nixon After testing the NeoFlow circuit out of the packet, I am not entirely happy with it, as the circuits appear to have a pre-configured PEEP setting.

Without more samples, we can't say if this is a random value or pre-determined by the manufacturing process.

Please read the attached report, but in summary, the out-of-packet PEEP was as follows:

6 cmH2O @ 5 l/min  
12 cmH2O @ 7 l/min  
27 cmH2O @ 10 l/min

In the sample I tested, setting the PEEP to its minimum value required 2 full turns of the PEEP cap anti-clockwise.

I believe that the default setting should be with minimum PEEP, as supplying circuits with pre-set PEEP increases the risk of the user making a clinical decision unintentionally.

Please can you address with Armstrong Medical

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18 Aug 2015 Steve Nixon

As discussed from my assessment, it is about 2.5 turns anticlockwise until the control disengages from the PEEP control thread. If it comes off the thread it may cause confusion with the operator as you have to apply pressure to push on the control in order to latch it into position again. Simply rotating the control clockwise will not re-engage the thread.

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18 Aug 2015 Steve Nixon  
email sent to Ross Armstrong:

Hi Ross

Please see attached a brief assessment of the Armstrong Medical NeoFlow by my colleague Michael Green.

From my assessment of samples, it is about 2.5 turns anticlockwise until the control disengages from the PEEP control thread. If it comes off the thread it may cause confusion with the operator, as you have to apply pressure to push on the control in order to latch it into position again. Simply rotating the control clockwise will not re-engage the thread.

So we have two concerns:

1) The circuits are delivered with PEEP set at a high level. Some nursing staff will not adjust the PEEP as this is usually the responsibility of the medic. We have had experience of a similar issue and want to try and avoid any future incident, so we would advocate that the circuits are delivered with minimal PEEP set, so as to be in a safe position.

2) The PEEP valve can be inadvertently disengaged.

Do you already have experience of the above and what is your standpoint and suggestions

Regards

Steve

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24 Aug 2015 Steve Nixon  
Had meeting with Ross this morning.  
he will send email:

1)Confirming that the NeoFlow circuits will be delivered set a minimum PEEP, with the PEEP value still engaged.

2)Confirming that if the PEEP valve is disengaged there is minimal risk as it can't be removed and the PEEP setting is still low. Also the valve is easily re-engaged.

3)He will supply comparative pressure data compared to the competition, showing that in terms of PEEP control the Neoflow is superior.

Ross also left a copy of a BioCote support pack booklet, he will also send a PDF version for us to utilize.

Next stage: we will order a small quantity of circuits for assessment. Ross said he would endeavour to protect our customer base.

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25 Aug 2015 Catrin Hird

Next Action Changed From Steve Nixon To Derek Lamb CE certificate required

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25 Aug 2015 Derek Lamb  
Emailed Armstrong

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10 Sep 2015 Steve Nixon

Next Action Changed From Derek Lamb To Steve Nixon PIP comparative graph generated by Armstrong Medical is attached.

NOTE: Armstrong Medical term PIP as Positive Inspiratory Pressure.

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10 Sep 2015 Steve Nixon  
Copy of email sent to Ross at Armstrong Medical.

Sorry for not getting back to you earlier Ross. Since we last talked we decided to carry out our own testing in regard to the PIP and PEEP functionality of the circuit and to compare it against our existing circuit and those from other suppliers. As we wished to supply your circuits together with our resuscitation units, we carried out a risk analysis, since your circuit would be a vital accessory.

Your circuit has several added value features and benefits, but it has a drawback - which we cant overlook. I know the likelihood of the situation arising is small and in practise it should not happen, nevertheless, there is a possibility of the risk occurring and if it ever did it would be a significant risk compared to our existing circuit. So under our ISO risk analysis our hands are tied.

As you know we have differing opinions on the PEEP functionality and presentation of results when the PEEP valve is effectively disengaged. However, there is a possibility of a user believing that the PIP & PEEP and have been set correctly, when in fact the displayed values may be erroneous due to gas leaking around the disengaged PEEP control valve. Then with an increase in occlusion pressure the PIP can spike to a much higher value. So this is what is considered as a clinical risk that we cannot overlook.

I understand and appreciate that you may well disagree with our comments, but I would like to leave the door open to purchasing circuits from you, if at some stage you implement a design change in regard to the operation of the PEEP valve.

Thank you for your support and for your visits, it is very much appreciated.

Kind regards

Steve

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16 Sep 2015 Steve Nixon

Next Action Changed From Steve Nixon To Derek Lamb As discussed, can the above be used as part of the risk assessment

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